AMENDED PATHOLOGY QUALITY ASSESSMENT REVIEW AND PWG COORDINATOR’S REPORT FOR LIFETIME CARCINOGENICITY STUDY OF VINYL CHLORIDE IN SPRAGUE-DAWLEY RATS CONDUCTED AT THE CANCER RESEARCH CENTER, EUROPEAN RAMAZZINI FOUNDATION FOR ONCOLOGY AND ENVIRONMENTAL SCIENCES, BOLOGNA, ITALY

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October 6, 2011
# Table of Contents

INTRODUCTION ............................................................................................................. 1
EXPERIMENTAL DESIGN AND METHODS ...................................................................... 2
RESULTS .......................................................................................................................... 3  
  Quality Assessment Review ...................................................................................... 4  
  Pathology Working Group Review ............................................................................ 4
CONFLICT OF INTEREST STATEMENT ......................................................................... 8
REASON FOR CHANGE(S) ............................................................................................ 9
SIGNATURE PAGE ......................................................................................................... 10

APPENDIX A  
  Slide Review Work Sheets - Males .................................................................. A-1 – A-25

APPENDIX B  
  Slide Review Work Sheets - Females ................................................................. B-1 – B-32

APPENDIX C  
  PWG Participants Curricula Vitae ..................................................................... C-1 – C-91
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AMENDED

PATHOLOGY QUALITY ASSESSMENT REVIEW AND
PATHOLOGY WORKING GROUP (PWG) COORDINATOR’S REPORT
FOR
LIFETIME CARCINOGENICITY STUDY
OF VINYL CHLORIDE
IN SPRAGUE-DAWLEY RATS

CONDUCTED AT

THE CANCER RESEARCH CENTER, EUROPEAN RAMAZZINI FOUNDATION
FOR ONCOLOGY AND ENVIRONMENTAL SCIENCES, BOLOGNA, ITALY

Quality Assessment Review: March 14-17, 2011
Date of the Pathology Working Group: April 4 – 8, 2011
PWG Coordinator: Robert R. Maronpot, DVM, MPH
Quality Assessment Pathologist: Peter C. Mann, DVM (EPL)
Study Diagnoses: Ramazzini Institute

PWG Participants:
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- Sabine Francke-Carroll, DVM, PhD (FDA)
- Peter Greaves, MBChB (Leicester University)
- Jerry F. Hardisty, DVM (EPL)
- Peter C. Mann, DVM (EPL)
- James B. Nold, DVM, PhD (Biotechnics)

PWG Observers:
- Steven Mog, DVM, PhD (FDA)
- Fiorella Belpoggi (Ramazzini Institute)
- Morando Soffritti, MD (Ramazzini Institute)
- Eva Tibaldi (Ramazzini Institute)
- Laura Falcioni (Ramazzini Institute)

INTRODUCTION

This report by Experimental Pathology Laboratories, Inc. (EPL®) presents the results of the Quality Assessment Review and the Pathology Working Group (PWG) which reviewed glass slides subsequent to the Quality Assessment Review of the Vinyl Chloride (VC) study. The VC study was conducted by the Ramazzini Institute by inhalation administration. The study started in 1974 and involved 318 rats.

Amended
(10/6/2011)
EXPERIMENTAL DESIGN AND METHODS

One day old Sprague-Dawley rats were exposed to vinyl chloride by inhalation for 4 hours per day, 5 days per week, for a total of 5 weeks and then held without further treatment for their lifetime. The numbers of animals used and their allocation to dose groups are shown in Table 1.

Table 1 – Study Design for Bioassay on Vinyl Chloride Administered in Drinking Water to Male and Female Sprague-Dawley Rats

<table>
<thead>
<tr>
<th>Dose Group</th>
<th>No. Rat and Sex</th>
</tr>
</thead>
<tbody>
<tr>
<td>10000 ppm</td>
<td>25 Males &amp; 21 Females</td>
</tr>
<tr>
<td>6000 ppm</td>
<td>18 Males &amp; 25 Females</td>
</tr>
<tr>
<td>0 ppm</td>
<td>109 Males &amp; 120 Females</td>
</tr>
</tbody>
</table>

Results of vinyl chloride study findings have been published previously by the Ramazzini Institute. The publication citations are as follows:


The peer review consisted of analysis of the Ramazzini Institute data and Quality Assessment (QA) of selected histopathology slides for the chronic lifetime study of vinyl chloride in Sprague-Dawley rats. The request was to review liver sections for hyperplastic and neoplastic changes from all male and female rats in all groups.
All slides with differences of opinion relating to the presence or absence of preneoplastic and neoplastic lesions in the liver between the study and reviewing pathologist were identified for possible review by the Pathology Working Group.

Slide Review Work Sheets were used to document the results of the QA review. These work sheets list in animal number order tissues that were examined by the QA pathologist. In addition, these work sheets list the study pathologist’s initial diagnosis for the tissues that were reviewed. The work sheets also record the QA pathologist’s comments indicating agreement with the Ramazzini pathologist’s diagnosis or a comment when a difference of opinion was noted.

The QA took place March 14-17, 2011 at the Ramazzini Institute. The number of slides examined during the QA review of the vinyl chloride study is listed in Table 2.

<table>
<thead>
<tr>
<th>Group</th>
<th>Males Slide Count</th>
<th>Females Slide Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>10000 ppm</td>
<td>42</td>
<td>35</td>
</tr>
<tr>
<td>6000 ppm</td>
<td>34</td>
<td>48</td>
</tr>
<tr>
<td>0 ppm</td>
<td>117</td>
<td>129</td>
</tr>
<tr>
<td>TOTAL</td>
<td>193</td>
<td>212</td>
</tr>
</tbody>
</table>

The Pathology Working Group (PWG) Panel met on April 6 - 7, 2011 to examine 144 liver sections from 82 rats.

RESULTS

All materials necessary for this review were readily available and well organized. All slides required to be examined by the QA pathologist were present. The histologic quality of the sections was considered to be very good with no deficiencies that interfered with the examination of the tissues present or the interpretation of histopathologic changes that were present. Neither the occasional cases with tissue autolysis nor the use of alcohol fixation presented diagnostic difficulties.
Quality Assessment Review

The quality assessment review resulted in several instances of changes in diagnostic nomenclature. Since the time this study was started in 1974, nomenclature for hepatoproliferative lesions has changed. Ramazzini study pathologist’s liver diagnoses of neoplastic nodules and nodular hyperplasia are either no longer used in the case of neoplastic nodule or only rarely used in the case of nodular hyperplasia. What was diagnosed as neoplastic nodule in past years is now considered either focus of cellular alteration or hepatocellular adenoma. Contemporary use of nodular hyperplasia is uncommon and such lesions are typically diagnosed as foci of cellular alteration or regenerative hyperplasia when there is evidence of antecedent or contemporary hepatotoxicity. Furthermore, liver tumors consisting of hepatocellular and cholangiocellular elements are now diagnosed as hepa
tocholangiomas or hepa
tocholgiocarcinomas based on changes in nomenclature occurring since this study was completed.

Slide Review Work Sheets used to document the results of the QA review are presented in Appendices A and B. These work sheets list in animal number order tissues that were examined by the QA pathologist from EPL. These work sheets list the initial diagnoses for the tissues which were reviewed and the QA pathologist’s agreement or difference of opinion. The QA review consisted of examination of all livers for presence of preneoplastic and neoplastic lesions. When different preneoplastic and neoplastic lesions were present in the same liver, each was diagnosed during the QA review.

Pathology Working Group Review

The primary focus during the PWG review was to confirm the presence of preneoplastic and neoplastic liver lesions for rats where there was a difference in diagnosis between the study and QA pathologist. Many of the diagnostic differences between study and QA pathologists are a reflection of nomenclature changes that have become generally accepted since the present study was completed. Diagnostic criteria for proliferative liver lesions used during the QA and PWG reviews are provided in the following references:


The PWG Panel members independently reviewed 144 liver slides from 82 rats without knowledge of prior diagnoses by the QA and study pathologists. The liver lesions were complex often with multiple distinct and merging tumors in the same liver and in the same tissue section. The hepatocellular carcinomas tended to have a more glandular component than what is typically seen. When the glandular pattern was sufficiently prominent, the PWG Panel preferred a diagnosis of hepatobiliary carcinoma, or more rarely hepatobiliary cholangioma. There were a number of borderline lesions, particularly involving the lesions ranging from eosinophilic focus of cellular alteration to adenoma to carcinoma. Basophilic foci were hard to identify since they were not tinctorially distinct. Consensus diagnoses for each type of lesion were recorded by the PWG Coordinator. The neoplastic lesions where there was agreement between the study and QA pathologist plus the consensus diagnoses from the PWG Panel review are presented in Tables 3 and 4 for males and females, respectively. Preneoplastic lesions including foci of cellular alteration and angiomatous hyperplasia are tabulated in Slide Review Worksheets in Appendices A and B. Aside from changes in nomenclature for liver lesions since completion of this study, there was good agreement between the QA and study pathologists. A high proportion of
livers reviewed by the PWG panel had foci of cellular alteration in addition to neoplastic lesions.

Table 3: Liver Tumors in Male Sprague-Dawley Rats Exposed by Inhalation to Vinyl Chloride for a Total of Five Weeks (Four Hours Per Day, Five Days per Week)

<table>
<thead>
<tr>
<th>Liver Lesion</th>
<th>0 ppm N = 104</th>
<th>6000 ppm N = 18</th>
<th>10000 ppm N = 25</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>SP(^a) QA/PWG(^b)</td>
<td>SP(^a) QA/PWG(^b)</td>
<td>SP(^a) QA/PWG(^b)</td>
</tr>
<tr>
<td>Hepatocellular Adenoma</td>
<td>0</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Hepatocellular Carcinoma</td>
<td>0</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Hepatocellular Adenoma and Carcinoma</td>
<td>0</td>
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<td>0</td>
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<td>Hepatocellular Adenoma or Carcinoma</td>
<td>0</td>
<td>9</td>
<td>13</td>
</tr>
<tr>
<td>Cholangioma</td>
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<td>9</td>
<td>9</td>
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<tr>
<td>Cholangiocarcinoma</td>
<td>0</td>
<td>0</td>
<td>1</td>
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<td>0</td>
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<td>0</td>
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<tr>
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<td>6</td>
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</tr>
<tr>
<td>Neoplastic Nodule</td>
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<td>2</td>
<td>7</td>
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</tbody>
</table>

\(^a\)Lesion frequency represents the study pathologist’s diagnoses.
\(^b\)Lesion frequency represents the QA and PWG Panel consensus.
Table 4: Liver Tumors in Female Sprague-Dawley Rats Exposed by Inhalation to Vinyl Chloride for a Total of Five Weeks (Four Hours Per Day, Five Days per Week)

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<th>10000 ppm N = 20</th>
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<td>QA/PWG&lt;sup&gt;b&lt;/sup&gt;</td>
<td>SP&lt;sup&gt;a&lt;/sup&gt;</td>
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<tr>
<td>Hepatocellular Adenoma</td>
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<td>0</td>
<td>5</td>
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<tr>
<td>Hepatocellular Carcinoma</td>
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<td>6</td>
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<td>Hepatocellular Adenoma or Carcinoma</td>
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<td>0</td>
<td>11</td>
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<td>Cholangioma</td>
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<td>0</td>
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<td>Cholangiocarcinoma</td>
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<tr>
<td>Neoplastic Nodule</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
</tbody>
</table>

<sup>a</sup>Lesion frequency represents the study pathologist’s diagnoses.

<sup>b</sup>lesion frequency represents the QA and PWG Panel consensus.
CONFLICT OF INTEREST STATEMENT

This statement is to certify that the person listed below, employed by Experimental Pathology Laboratories, Inc., participated in the QA review and Pathology Working Group (PWG) from the Lifetime Carcinogenicity Study of Vinyl Chloride in Sprague-Dawley Rats conducted at the Cancer Research Center, European Ramazzini Foundation for Oncology and Environmental Sciences. He has not been involved in any aspect of the study for any organization other than NTP which conducted the study nor the generation and/or evaluation of materials or data which were reviewed prior to the receipt of materials from the study lab. Hence, his participation in the PWG poses no apparent or actual conflict of interest.

[Redacted]

ROBERT R. MARONPOT, D.V.M., M.S., M.P.H.
Diplomate, ACVP, ABT
PWG Coordinator

6 Oct 2011

RRM:asc
REASON FOR CHANGE(S)

Pathology Quality Assessment
Review and PWG Coordinator’s Report
For
Lifetime Carcinogenicity Study
Of Vinyl Chloride
In Sprague-Dawley Rats

The amended report is being issued to add the study pathologist’s data to Tables 3 and 4, on pages 6 and 7, respectively of the amended report and to include minor editorial changes to the text of the narrative portion of the final report submitted on August 10, 2011. No changes have been made to the Slide Review Work Sheets presented in Appendices A and B.

[Redacted]

ROBERT R. MARONDOT, D.V.M., M.S., M.P.H.
Diplomate, ACVP
Senior Veterinary Pathologist

6 Oct 2011

RRM/asc
PATHOLOGY WORKING GROUP (PWG) PARTICIPANTS:

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[Redacted]

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[Redacted]

CHARLES CLIFFORD, DVM, PhD
Diplomate, ACVP
[Redacted]

JAMES B. NOLD, DVM, PhD
Diplomate, ACVP
[Redacted]

PETER C. MANN, DVM
Diplomate, ACVP
[Redacted]

JERRY F. HARDISTY, DVM
Diplomate, ACVP
APPENDIX A

SLIDE REVIEW WORK SHEETS

MALE
SLIDE REVIEW WORKSHEET

<table>
<thead>
<tr>
<th>CID Number</th>
<th>Histology Number</th>
<th>No Of Slides</th>
<th>Study Pathologist's Diagnoses</th>
<th>Reviewing Pathologist's Comments</th>
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<th>Action To Be Taken</th>
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## SLIDE REVIEW WORKSHEET

**Study Title**: VINYL CHLORIDE  
**Chemical #**

**Laboratory**: CRC  
**CAS #**

**Group**: 3M  
**Dosage**: 0 PPM

**Sex & Species**: MALE  
**Sacrifice**: SPRAGUE DAWLEY RAT

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Chemical #
Laboratory CRC
Group 3M
Sex & Species MALE
Species SPRAGUE DAWLEY RAT
Dosage 0 ppm
Sacrifice

**CID 1377:**
- Study Title: VINYL CHLORIDE
- Laboratory: CRC
- Group: 3M
- Sex & Species: MALE
- Species: SPRAGUE DAWLEY RAT
- Dosage: 0 ppm
- Sacrifice

**CID 1378:**
- Study Title: VINYL CHLORIDE
- Laboratory: CRC
- Group: 3M
- Sex & Species: MALE
- Species: SPRAGUE DAWLEY RAT
- Dosage: 0 ppm
- Sacrifice

**CID 1379:**
- Study Title: VINYL CHLORIDE
- Laboratory: CRC
- Group: 3M
- Sex & Species: MALE
- Species: SPRAGUE DAWLEY RAT
- Dosage: 0 ppm
- Sacrifice

**CID 1380:**
- Study Title: VINYL CHLORIDE
- Laboratory: CRC
- Group: 3M
- Sex & Species: MALE
- Species: SPRAGUE DAWLEY RAT
- Dosage: 0 ppm
- Sacrifice

**CID 1381:**
- Study Title: VINYL CHLORIDE
- Laboratory: CRC
- Group: 3M
- Sex & Species: MALE
- Species: SPRAGUE DAWLEY RAT
- Dosage: 0 ppm
- Sacrifice

**CID 1382:**
- Study Title: VINYL CHLORIDE
- Laboratory: CRC
- Group: 3M
- Sex & Species: MALE
- Species: SPRAGUE DAWLEY RAT
- Dosage: 0 ppm
- Sacrifice

**CID 1383:**
- Study Title: VINYL CHLORIDE
- Laboratory: CRC
- Group: 3M
- Sex & Species: MALE
- Species: SPRAGUE DAWLEY RAT
- Dosage: 0 ppm
- Sacrifice

**CID 1384:**
- Study Title: VINYL CHLORIDE
- Laboratory: CRC
- Group: 3M
- Sex & Species: MALE
- Species: SPRAGUE DAWLEY RAT
- Dosage: 0 ppm
- Sacrifice

**CID 1385:**
- Study Title: VINYL CHLORIDE
- Laboratory: CRC
- Group: 3M
- Sex & Species: MALE
- Species: SPRAGUE DAWLEY RAT
- Dosage: 0 ppm
- Sacrifice

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- LIVER - DIFFUSED HYPER, PRESENT
- LIVER - FATTY CHANGE, PRESENT
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**PWG Coordinator’s Comments:**

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**Action To Be Taken:**
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**Study Title**: VINYL CHLORIDE  
**Chemical #**:  
**Laboratory**: CRC  
**Group**: 3M  
**Sex & Species**: MALE SPRAGUE DAWLEY RAT  
**Dosage**: 0 PPM  
**Sacrifice**:  

**CID**

**Number**

**Histology**

**Number**

**No Of Slides**

**Study Pathologist’s Diagnoses**

**Reviewing Pathologist’s Comments**

**PWG Coordinator’s Comments**

**PWG Consensus**

**Action To Be Taken**

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**Study Title**: VINYL CHLORIDE  
**Chemical #**:  
**Laboratory**: CRC  
**CAS #**:  
**Group**: 3M  
**Dosage**: 0 PPM  
**Sex & Species**: MALE  
**Species**: SPRAGUE DAWLEY RAT  
**Sacrifice**: TMT 5

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**Laboratory**: CRC  
**Group**: TMT 3  
**Sex & Species**: MALE SPRAGUE DAWLEY RAT  
**Chemical #**:  
**CAS #**:  
**Dosage**: 6,000 PPM  
**Sacrifice**:  

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**SPRAGUE DAWLEY RAT**

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**Laboratory**: CRC  
**Group**: 1M  
**Sex & Species**: MALE  
**Chemical**: VINYL CHLORIDE  
**CAS #**: 1  
**Dosage**: 10,000 PPM  
**Sacrifice**: TMT 1  

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**Study Title**: VINYL CHLORIDE  
**Laboratory**: CRC  
**Group**: 1M  
**Sex & Species**: MALE SPRAGUE DAWLEY RAT  
**Chemical #**:  
**CAS #**:  
**Dosage**: 10,000 PPM  
**Sacrifice**:  

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APPENDIX B

SLIDE REVIEW WORK SHEETS

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**Study Title**: VINYL CHLORIDE  
**Laboratory**: CRC  
**Group**: 3F  
**Sex & Species**: FEMALE SPRAGUE DAWLEY RAT  
**Chemical #**: VINYL CHLORIDE  
**CAS #**:  
**Dosage**: 0 PPM  
**Sacrifice**: TMT 6

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### SLIDE REVIEW WORKSHEET

**Study Title:** VINYL CHLORIDE  
**Laboratory:** CRC  
**Group:** 3F  
**Sex & Species:** FEMALE  
**Species:** SPRAGUE DAWLEY RAT  
**Sacrifice:** TMT 6  
**Chemical #:** CAS #  
**Dosage:** 0 PPM  

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**Laboratory**: CRC  
**Group**: 3F  
**Sex & Species**: FEMALE  
**Sprague Dawley Rat**  
**Chemical #**: VINYL CHLORIDE  
**CAS #**:  
**Dosage**: 0 PPM  
**Sacrifice**:  

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SLIDE REVIEW WORKSHEET

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Laboratory: CRC
Group: 3F
Sex & Species: FEMALE  SPRAGUE DAWLEY RAT
Chemical #: VINYL CHLORIDE
CAS #: 1266
Dosage: 0 PPM
Sacrifice: TMT 6

CID Number: 1266
Histology Number: 1
No Of Slides: 1
Study Pathologist's Diagnoses: LIVER - NORMAL
Reviewing Pathologist's Comments: AGREE
PWG Coordinator's Comments: NOT REVIEWED
PWG Consensus: NOT REVIEWED
Action To Be Taken: blank = No Change Required

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Histology Number: 1
No Of Slides: 1
Study Pathologist's Diagnoses: LIVER - DIFFUSED HYPER, PRESENT
Reviewing Pathologist's Comments: LIVER - BASOPHILIC FOCUS (-)
PWG Coordinator's Comments: NOT REVIEWED
PWG Consensus: NOT REVIEWED
Action To Be Taken: blank = No Change Required

CID Number: 1268
Histology Number: 1
No Of Slides: 1
Study Pathologist's Diagnoses: LIVER - NORMAL
Reviewing Pathologist's Comments: AGREE
PWG Coordinator's Comments: NOT REVIEWED
PWG Consensus: NOT REVIEWED
Action To Be Taken: blank = No Change Required

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No Of Slides: 1
Study Pathologist's Diagnoses: LIVER - DIFFUSED HYPER, PRESENT
Reviewing Pathologist's Comments: NOT PRESENT IN SECTION (-)
PWG Coordinator's Comments: NOT REVIEWED
PWG Consensus: NOT REVIEWED
Action To Be Taken: blank = No Change Required

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No Of Slides: 2
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Reviewing Pathologist's Comments: AGREE
PWG Coordinator's Comments: NOT REVIEWED
PWG Consensus: NOT REVIEWED
Action To Be Taken: blank = No Change Required

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Study Pathologist's Diagnoses: LIVER - NODULAR HYPERP, PRESENT
Reviewing Pathologist's Comments: LIVER - EOSINOPHILIC FOCUS (-)
PWG Coordinator's Comments: NOT REVIEWED
PWG Consensus: NOT REVIEWED
Action To Be Taken: blank = No Change Required
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**Study Title:** VINYL CHLORIDE  
**Laboratory:** CRC  
**Group:** 3F  
**Sex & Species:** FEMALE SPRAGUE DAWLEY RAT  

**Chemical #:** VINYL CHLORIDE  
**CAS #:**  
**Dosage:** 0 PPM  

**Sacrifice:** TMT 6

*Action To Be Taken: blank = No Change Required*
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**Study Title:** VINYL CHLORIDE  
**Laboratory:** CRC  
**Group:** 3F  
**Sex & Species:** FEMALE  
**Species:** SPRAGUE DAWLEY RAT  
**Chemical #:** TMT 6  
**Dosage:** 0 PPM  
**Chemical Name:** CRC  
**CAS #:**  
**Sacrifice:**
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**Chemical**: VINYL CHLORIDE  
**Laboratory**: CRC  
**Group**: 3F  
**Sex & Species**: FEMALE SPRAGUE DAWLEY RAT  
**Chemical #**: TMT 6  
**Dosage**: 0 PPM  
**Sacrifice**:
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**Study Title**: VINYL CHLORIDE  
**Laboratory**: CRC  
**Group**: 3F  
**Sex & Species**: FEMALE  
**Sacrifice**: SPRAGUE DAWLEY RAT  
**Chemical #**: VINYL CHLORIDE  
**CAS #**:  
**Dosage**: 0 PPM  
**Sacrifice**:  

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# SLIDE REVIEW WORKSHEET

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**Study Title**: VINYL CHLORIDE  
**Laboratory**: CRC  
**Group**: 3F  
**Sex & Species**: FEMALE SPRAGUE DAWLEY RAT  
**Chemical #**: CRC  
**CAS #**: TMT  
**Dosage**: 0 PPM  
**Sacrifice**:
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**Study Title**: VINYL CHLORIDE  
**Laboratory**: CRC  
**Group**: 3F  
**Sex & Species**: FEMALE SPRAGUE DAWLEY RAT  
**Chemical #**: VINYL CHLORIDE  
**CAS #**: 1319  
**Dosage**: 0 PPM  
**Sacrifice**: TMT 6

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**Laboratory**: CRC  
**Group**: 2F  
**Sex & Species**: FEMALE SPRAGUE DAWLEY RAT  
**Chemical #**: CRC  
**CAS #**: 2F  
**Dosage**: 6,000 PPM  
**Sacrifice**: TMT 4

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# SLIDE REVIEW WORKSHEET

**Study Title**: VINYL CHLORIDE  
**Laboratory**: CRC  
**Group**: 1F  
**Sex & Species**: FEMALE SPRAGUE DAWLEY RAT  
**Chemical #**:  
**CAS #**:  
**Dosage**: 10,000 PPM

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**SLIDE REVIEW WORKSHEET**

**Study Title**: VINYL CHLORIDE  
**Laboratory**: CRC  
**Group**: 1F  
**Sex & Species**: FEMALE  
**Sacrifice**: SPRAGUE DAWLEY RAT  
**Chemical #**: VINYL CHLORIDE  
**CAS #**: CRC  
**Dosage**: TMT 2  
**10,000 PPM**
**SLIDE REVIEW WORKSHEET**

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**Study Title:** VINYL CHLORIDE  
**Laboratory:** CRC  
**Group:** 1F  
**Sex & Species:** FEMALE SPRAGUE DAWLEY RAT  
**Chemical #:**  
**CAS #:**  
**Dosage:** 10,000 PPM  
**Sacrifice:** TMT 2
### SLIDE REVIEW WORKSHEET

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<th>Reviewing Pathologist's Comments</th>
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<th>PWG Consensus</th>
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**Study Title**: VINYL CHLORIDE  
**Laboratory**: CRC  
**Group**: IF  
**Sex & Species**: FEMALE SPRAGUE DAWLEY RAT  
**Chemical #**: VINYL CHLORIDE  
**CAS #**:  
**Dosage**: 10,000 PPM  
**Sacrifice**: TMT 2  

**Histology**

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<th>Study Pathologist's Diagnoses</th>
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**PWG Coordinator's Comments**

- **AGREE WITH STUDY PATHOLOGIST**
- **AGREE**
- **NOT REVIEWED**
APPENDIX C

PWG PARTICIPANTS
CURRICULA VITAE
Charles B. Clifford, D.V.M., Ph.D.

email charles.clifford@crl.com

Present Position

Director, Pathology and Technical Services, Charles River

Education

1974 B.S. (Zoology) Michigan State University
1977 D.V.M. Michigan State University
1981-1983 Pathology Residency Walter Reed Army Institute of Research
1988 Ph.D. (Pathology) Cornell University
minors in Immunology and Cell Biology

Professional and Scientific Societies

American College of Veterinary Pathologists
(Diplomate, by examination) 1983 - present

Society of Toxicologic Pathologists
(Full Member) 1989 - present

American Veterinary Medical Association 1981 - present

American Association of Laboratory Animal Science 1992 - present
Experience

1977-1978 Veterinary Officer, Veterinary Detachment, Bayonne, NJ. Supervised approximately 30 civilian and military personnel who inspected most subsistence shipped to the U.S. military in Europe. Conducted sanitary inspection of 5 commissaries and over 80 civilian food processors and suppliers in New York City, Long Island and northern New Jersey. Responsible for zoonosis control at 4 Army posts.

1978 Assistant Officer-in-Charge, Team D, 106th Medical Detachment, Pusan, Republic of Korea. Supervised inspection of all subsistence shipped to the U.S. Army in Korea, and managed the only two military veterinary clinics within a 90 mile radius.

1978-1979 Officer-in-Charge, Team A, 106th Medical Detachment, Ouijongbu, Republic of Korea. Supervised all food inspection for U.S. troops stationed north of Seoul, including along the DMZ, public health consultation for the 2nd Infantry Division. Also was Assistant Chief and Surgeon for the U.S. Army veterinary clinic in Seoul.

1979-1980 Course Director, US Army Animal Care Specialist School, Washington, DC, the only school in the U.S. Army to train Animal Health Technicians. Was responsible for course content and administration, counseling and supervision of 5 faculty members, and 120 students per year. Taught courses in pathology, anesthesia, radiology, and the Cardiovascular, Respiratory and Gastrointestinal System.

1980-1983 Pathology Resident, Division of Pathology, Walter Reed Army Institute of Research. Provided collaborative histopathology support to the institute, including studies of renal toxicity, pulmonary trauma and toxicity using rodent, lagomorph, canine, and primate models. Served as diagnostic pathologist for the Institute’s rodent and primate colonies. Completed all requirements for the board examination of the American College of Veterinary Pathologists.

1982-1984 Assistant Senior Army Social Aide to the President of the United States for White House functions, such as receptions and State dinners.

1983-1984 Staff Pathologist, Division of Pathology, Walter Reed Army Institute of Research. Developed a rat model and conducted independent research on pathogenesis and healing of pulmonary lesions due to concussive pressure waves. Collaborated in studies of hemorrhagic shock, military systems hazards assessment, and toxicopathology of anti-schistosomal drugs. Assisted in training of 3 pathology residents per year in preparation of the veterinary pathology board examination.

1984-1987 Research Assistant (doctoral student), Cornell University. Conducted original research on the ontogeny of neutrophil function and the inflammatory response, comparing fetuses, neonates, and adults. Designed a novel model of in utero pulmonary inflammation in the sheep, permitting repetitive blood sampling and bronchoalveolar lavage. Initiated and developed a histopathology training series for
3 veterinary pathology residents from non-English speaking countries. Each resident then successfully completed the veterinary pathology board examination. Completed all requirements for Doctor of Philosophy degree.

1987-1991  Research Pathologist and Assistant Chief of Pathology, Lettenman Army Institute of Research. Supervised the Institute's postmortem and clinical pathology laboratories. Conducted original research in distribution and toxicity of purified modified hemoglobin solutions. Collaborated with other scientists in model design and pathology support of Good Laboratory Practices Act-compliant toxicity studies (principal pathologist), pathogenesis of neurovascular trauma, hemorrhagic shock and perfusion injury, wound healing, and pre-clinical testing of candidate resuscitative fluids. Served on a rotating duty as diagnostic pathologist for animal postmortem examinations. Member of the Institute's Animal Care and Use Committee.

1991-2001  Staff Officer, US Army Medical Research and Materiel Command. Two weeks annual duty as a senior staff member in office with budget and program oversight of all Army biomedical research concerning biological and chemical agents, >$100 million/annum. Duties included technical review of research proposals, analysis and synopsis of diverse research projects for senior pentagon management. Retired as Colonel.

1991-1993  Senior Pathologist, Charles River Laboratories. Oversee all aspects of pathology support of the world's largest supplier of laboratory animals, with approximately $600 million in annual sales and production facilities in the U.S. and more than 10 other countries. Collaborate in the definition of new animal models, including genetically engineered animals. Supervise extramural development of new diagnostic technologies. Design and conduct pathology service protocols in support of biotechnology and pharmaceutical customers. Address and resolve customer concerns regarding unexpected research findings or other pathology-related issues. Key professional for CRL swine xenotransplantation efforts.

1993-present Director, Pathology and Technical Services.  (additional duties to above) Supervise two other pathologists and the Charles River Technical Assistance Department, which provides information to customers concerning normative data, test procedures, husbandry, health, and all other matters relating to laboratory animals. Oversee corporate toxicology consultant, preparation of technical and reference papers on Historical Control Data.

2001-2003  (additional duties) Direct responsibility for Contract Research Services department, approximately $2 million annual revenue. Specialty areas include oncology, vaccine testing, novel imaging studies.
Licensure

Michigan, #5124, 1977 to present.

Inventions

Hairless Immunodeficient Mouse Model (U.S. application no. 12/047,948)

PUBLICATIONS


30. [In Press withheld under Exemptions B4 and B6]


ABSTRACTS


Curriculum Vitae

Dr. Sabine FRANCKE-CARROLL
Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

DHHS/CFSAN/FDA/ OFAS/ Senior Science and Policy Staff / Pathology
5100 Paint Branch Parkway HFS-205
College Park MD 20740
(301) 436-1308

EDUCATION:
Ph.D., The Ohio State University, Columbus, OH, USA
Applied Veterinary Pathology Residency, The Ohio State University, Columbus, OH, USA
Dr. Vet. Med., Justus-Liebig University, Giessen, Germany
D.V.M., Justus-Liebig University, Giessen, Germany

PROFESSIONAL ORGANIZATIONS AND MEMBERSHIPS:
Recognized Fellow of the International Academy of Toxicologic Pathology (IATP; 2010 - present)
European Society of Toxicologic Pathology (ESTP; 2009 – present)
US Society of Toxicologic Pathology (STP; 1998 – present)
American College of Toxicology (ACT; 1999 - present)
Association of Government Toxicologists (AGT; 2000- present) – President Elect (2009-11)
Charles Louis Davis D.V.M. Foundation for the Advancement of Veterinary and Comparative Pathology (2000 – present)

United States and Canadian Academy of Pathology, Inc. (USCAP 2000-2010)
American Association for the Advancement of Science (AAAS 1992-2010)
National Society for Histotechnology (NSH 2004-2009)

PROFESSIONAL EXPERIENCE:

CURRENT DUTIES:
Expert Toxicologic Veterinary Regulatory Review Pathologist, Senior Science and Policy Staff / Pathology
Department of Health and Human Services / FDA / CFSAN / OFAS / College Park, MD.
4/10 – present
The incumbent in the Office of Food Additive Safety (OFAS) in CFSAN is recognized by FDA as subject matter expert for Toxicologic Veterinary Regulatory Review Pathology (Veterinary Officer / Pathologist) and serves as an authoritative expert in her field, conducting independent, in-depth regulatory reviews and complex safety evaluations of pathology data from regulatory submissions from all FDA Centers. The incumbent performs independent histo-pathological slide evaluations and serves as authoritative expert in regulatory toxicologic veterinary pathology on Center-, Inter Agency-, and national / international professional committees and provides a regulatory perspective when serving on Pathology Working Groups (PWGs) convened to resolve complex pathology issues.
Supervisor: Dennis Keefe, Ph.D., (Director, SSPS, OFAS, CFSAN/FDA)

Senior Toxicologic Veterinary Pathologist, Senior Science and Policy Staff / Pathology
Department of Health and Human Services / FDA / CFSAN / OFAS / College Park, MD.
2/2007- 3/10. The incumbent serves in the Office of Food Additive Safety (OFAS) in CFSAN as Toxicologic Veterinary Pathologist (Veterinary Officer / Pathologist) conducting independent, in-depth regulatory reviews and complex safety evaluations of pathology data from regulatory submissions from all FDA Centers. The incumbent performs a wide range of administrative functions pertaining to the budget process, property management and pathology contract management.
Supervisor: Dennis Keefe, Ph.D., (Director, SSPS, OFAS, CFSAN/FDA)

Acting Branch Chief, Pathology Branch
Department of Health and Human Services / FDA / CFSAN / OSAS / DGSS / Pathology Branch, College Park, MD.
1/2005-2/2007 Center-wide Reorganization. The incumbent is an experienced regulatory reviewer and applies in-depth professional knowledge and skills as Veterinary Medical Officer / Pathologist conducting independent safety evaluations of pathology data from regulatory petitions for the Division of General Scientific Support (DGSS).

The incumbent manages independently the Pathology Branch and the associated histopathology laboratory, performing a wide range of administrative functions pertaining to daily operations (such as the budget process, property management and contract management). The Pathology Branch and the Pathology Laboratory provide a full range of pathology support functions.
Curriculum Vitae

Dr. Sabine FRANCKE-CARROLL
Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

PROFESSIONAL EXPERIENCE (contd.):
for requesting Offices/researchers such as pathology protocol design, monitoring animal-study in-life-phases, performing necropsies, guiding the tissue processing, evaluating histological glass slides and reporting of pathology data. The incumbent instructs and trains laboratory associated personnel and adjunct students from the University of Maryland. The incumbent is solely responsible for the development and application of all immuno-histopathological services provided by the Pathology Laboratory.
Supervisor: Prem Dua, D.V.M., Ph.D., (Director, DGSS, OSAS, CFSAN/FDA)

Senior Staff Toxicologic Pathologist
Department of Health and Human Services / FDA / CFSAN / OSAS / DGSS / Pathology Branch, College Park, MD
01/2002-12/2004. The incumbent assists the Director of the Division of General Scientific Support (DGSS) with regulatory (food petition) reviews. To do this the incumbent applies knowledge of FDA laws/regulations and extensive experience in pathology data analysis. The incumbent is further involved in administrative matters pertaining to the operation of the Pathology Branch, e.g. the zero based budgeting process. The incumbent’s significant research experience involves her extensively as Co-principal investigator in several research projects with Center and/or adjunct scientists from the University of Maryland (UMD). The incumbent serves as student mentor and instructor to laboratory personnel and UMD/JIFSAN students, and promotes the development of immuno-histopathological services provided by the Pathology Laboratory.
Supervisors: Fred Hines, D.V.M., (Pathology Branch Chief), Prem Dua D.V.M., Ph.D., (DGSS Director)

Staff Toxicologic Pathologist
Department of Health and Human Services / FDA / CFSAN / OSAS / DGSS / Pathology Branch, College Park, MD
01/2001 – 12/2002. The incumbent provides histo-pathological analysis and support to requesting researchers associated with Governmental Offices (e.g. OARSA) and/or joint facilities such as the University of Maryland (under the umbrella of the Joint Institute for Food Safety and Applied Nutrition (JFSAN)). The incumbent participates as Immuno-pathologist and/or as Co-principal-investigator in protocol design, monitors animal-study in-life-phases, performs necropsies, guides the tissue processing, evaluates histological slides and conducts the final pathology-relevant reporting of assigned animal research studies. The incumbent initiates the development of immuno-histopathological services provided by the Pathology Laboratory.
Supervisors: Fred Hines, D.V.M., (Pathology Branch Chief), Prem Dua D.V.M., Ph.D., (DGSS Director)

Toxicologic Pathologist, Novartis Pharmaceuticals Inc. East Hanover, NJ.
11/98 – 11/2000. The incumbent generates and evaluates pathology data of assigned acute, subacute and chronic preclinical drug-safety studies which also entailed partial, direct/indirect supervision of technical personnel assigned to these studies. The incumbent is assigned to projects with standard design and/or those requiring an appropriate level of interpretive experience and knowledge. A current knowledge of recent advances and new equipment/procedures is important to achieve optimum results. At the conclusion of each study, the incumbent participates in the data review/analyses to determine target organ toxicity. The incumbent participates in the study design and in the evaluation and implementation of new procedures to improve preclinical drug-safety operations. The incumbent is a member of scientific boards, project teams, and advisory committees and performs other duties as assigned by upper management.
Supervisor: Dr. Pritam Sahota, D.V.M, Ph.D.

Veterinary Research Pathologist, Pathology Associates International (PAI). Immunology and Molecular Pathology Division Frederick, MD 21701
09/1996 – 98. The incumbent evaluates designs and interprets studies assessing the cross-reactivity characteristics of monoclonal antibodies in human and animal tissues (in vivo/in vitro exposure), the localization of monoclonal antibodies by means of immuno-labeling techniques and conducts development and application of molecular and cellular histopathologic technology to characterize and resolve mechanistic problems associated with biopharmaceutical product development.
Supervisor: Bill Hall, V.M.D., Ph.D.

Updated 02/08/11
Curriculum Vitae

Dr. Sabine FRANCKE-CARROLL
Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

PROFESSIONAL EXPERIENCE (contd.):

Graduate Research Associate (Ph.D. / Veterinary Pathologist), The Ohio State University, Department of Veterinary Biosciences, Columbus, Ohio
1992-1996 Research conducted evaluates anti-retroviral drug-effects (mainly AZT) on cellular immune responses and immune-cell precursor frequencies. Effector-cell frequency analysis, by limiting dilution analysis (LDA), allows not only qualitative assessment but also quantitation of the effects noted. Two animal models, an outbred feline model for retroviral infection and an inbred mouse model for allograft rejection are utilized in these studies. Research activities: Histopathology, immunology, retro-virology, in-vivo and in-vitro drug testing, immunohistochemistry, vaccine development, cell culture and molecular biology.
The thesis advisor: Lawrence E. Mathes, Ph.D., Professor.

Graduate Teaching Associate and Resident (Veterinary Pathologist / Ph.D.)
1990-1992 (continued services during Ph.D training until 1996) The Ohio State University
Department of Veterinary Biosciences
Columbus, Ohio

Graduate Assistant (Dr.med.Vet.)
1988-1990 Justus-Liebig University
Giessen, Germany
Research performed to obtain a “Dr. Vet. Med.” degree centers on the immunohistologic characterization of the cellular immune response to bacterial infection with Coxiella burnetii in a murine model. Results illustrated that cellular mechanisms are crucially involved in the pathogenesis of chronic infection with C. burnetii.
The thesis advisor: Dr. Wolfgang Baumgaertner, D.V.M., Ph.D., Professor.

Graduation from Veterinary School (DVM)
1988 Justus-Liebig University
Giessen, Germany

LEADERSHIP EXPERIENCE:

- Elected board member to IATP 2011: Vice president 2011-13; President 2013-15
- Recognized as Fellow IATP (International Academy of Toxicologic Pathology) 2009.
- FDA recognized (Agency Peer Review) Expert for Toxicologic Veterinary Regulatory Review Pathology (April 2011)
- President Elect of the Association of Government Toxicologists (AGT) term 2010-2011
- Councilor to the Board of the Association of Government Toxicologists (AGT), 2006 & 2008
- CFSAN Immunotox Redbook working group; chair
- STP SRPC Regulatory Liaison since 2005 till present
  - Hepatic Enzyme Induction working group liaison since 2007/ chair – Dec 2008-10
  - Historical Control Data working group SRPC liaison, 2006-2009
- Pathology Laboratory Chief, and Acting Pathology Branch Chief; providing training, instructions and guidance to Laboratory Technicians and visiting scientists from UMD, regarding duties and functions of the Pathology Branch and its Laboratory.
- Mentor to JIFSAN students; Mentor to UMD and Pathology Laboratory students.
- Histopathology mentor and instructor for Laboratory Biologist; training included pathology terminology, histology, histopathology, tissue trimming, tissue processing, preparation of paraffin blocks, microtoming, H&E staining of routine slides, Immunohistochemical staining, archiving, laboratory administrative work and reagent ordering.

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Curriculum Vitae

Dr. Sabine FRANCKE-CARROLL
Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

SERVICES AND RESPONSIBILITIES:

- Regulatory liaison to the Scientific Regulatory and Policy Committee (SRPC) of the Society of Toxicologic Pathology (STP) since 2005
  - SRPC liaison to the Historical Control Data working group; 2006-09 - Best Practice manuscript published TP 2009; 37(5) 679-93.
  - SRPC liaison to the Joint Regulatory Affairs Committee (JRAC) between STP and the American College of Veterinary Pathology (ACVP); since 2006 - 2009.
  - Invited Member of the STP Regulatory Forum editorial group for the Journal of Toxicologic Pathology since 2007 – ongoing.
- CFSAN Immunotox Redbook committee since 2006
  - Chair: Dec 07 – ongoing.
- Association of Government Toxicologists (AGT)
  - Board member councilor 2005-07; elected for second term 2008; President elect 2009-10; President 2010-11; Past President 2011-12 - 3 year leadership commitment - ongoing.
- Acting Chief of the Pathology Branch and Laboratory / DGSS (1/2005- until CFSAN reorganization 2/2007).
- CFSAN Cancer Assessment Committee (CAC) Member – Pathologist – since 2004.
- CFSAN Pathology Services and Archiving Contract Project Officer since 2006 – recertified as COTR July 31, 2009.
- Property Management Officer 2005-07.
- CFSAN Science Council Committee Member since 2004.
  - SC Scientific Dissent Resolution policy draft subcommittee 2007-09.
- CFSAN Toxicology Redbook Committee Member since 2003.
- Joint Institute for Food Safety and Applied Nutrition (JIFSAN) steering Committee Member 2002-'07. And JIFSAN Grant – Pathology Support Collaborator to the University of Maryland (UMD), Department of Food Science.

AWARDS / Professional Recognitions

- Recognized as Fellow IATP (International Academy of Toxicologic Pathology) 2009.
- FDA / CFSAN Outstanding Customer Service Award, Office of Food Additive Safety for pathology support to CDRH on the histopathological evaluation of mouse tissues for the distribution of nano-material, June 2008.
- FDA and Center-level Crosscutting Award that includes CFSAN Employees, FDA Melamine Award, Adulterated protein investigations, analysis, planning, scientific review and emergency response team for exemplary performance to protect the public health from adulterated protein through actions of investigations, sample analyses, method development, assignment, planning, emergency response, scientific review and risk assessment, June 2008.
- FDA / CFSAN Honor Award: Aspartame Carcinogenicity Review Team, Office of Food Additive Safety for exceptional performance in evaluating the results of a number of carcinogenicity studies on aspartame, including the high-profile European Ramazzini Foundation study, June 2008.
- FDA Outstanding Service Award for outstanding performance while participating on an expert pathology review panel in response to an Inter-Center pathology support request from CDER June 2007.
- FDA Outstanding Service Award for outstanding performance in the regulatory review of pathology issues and in providing critical pathology support to the Office of Food Additive Safety June 2006.
- FDA Outstanding Service Award for sustained superior performance in evaluating and resolving complex regulatory pathology review issues as well as supporting collaborating scientists June 2005.
- FDA Outstanding Service Award for sustained superior performance in the evaluation of substantial and voluminous regulatory and experimental pathology data June 2004.
- Team Award as member of the OARSA Food Allergenicity Team for outstanding team effort in successfully completing pilot studies to evaluate a unique animal model for the study of human food allergenicity June 2003.
- FDA Outstanding Service Award for sustained superior performance in the Pathology Branch instituting a food-allergy rat model, leveraging with the UMD and establishing a IH laboratory June 2003.

Updated 02/08/11

4/7

C-013
Curriculum Vitae

Dr. Sabine FRANCKE-CARROLL
Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

- Quality Performance Award for developing methods to quantify “altered crypt foci” in the colon of rats July 2002
- Quality Performance Award for Pathology support services with the University of Maryland (UMD) June 2002

PUBLICATIONS AND PRESENTATIONS:

Technical Reports: lists on
- regulatory review projects (upon request)
- regulatory research projects (upon request).

Poster / Journal presentations and Talks:


Updated 02/08/11
PUBLICATIONS AND PRESENTATIONS (contd.)


Hinton D.M., Lorenzo M.E., Harper S.B., Francke-Carroll S., O'Neill R.K., Chirtel S.J., Calvo M.S. An In-Bred Rat Strain (the FDA “Asthmatic Rat”) for Predicting the Allergic Potential of Proteins and for Evaluating the Efficacy of Drugs and Dietary Supplements in Respiratory (Asthmatic) and Cardiovascular Studies Poster presentation (Board Number B-08) at the 10th Annual FDA Science Forum, 2004, Washington Convention Center, Washington DC.


Francke-Carroll S., Daly K., Wang T. and Magnuson B.A. Underlying age-related liver pathology increases azoxymethane toxicity in F344 female rats in an aging study on colon cancer chemoprevention with dietary soy. Website publication (Board Number D-PO-01) for the 10th Annual FDA Science Forum, 2004, Washington Convention Center, Washington DC.


Updated 02/08/11
Vitae
Dr. Sabine FRANCKE-CARROLL
Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

PUBLICATIONS AND PRESENTATIONS (contd.)


Francke S. Evaluation of the Immunomodulatory effects of the anti-retroviral drug Zidovudine (AZT). Presented in partial fulfillment of the requirements for the degree Doctor of Philosophy in the Graduate School of The Ohio State University. The Ohio State University, Columbus, OH, USA, 1996.


Updated 02/08/11
Dr Greaves is a medical graduate trained in laboratory medicine, specialising in human and experimental histopathology and toxicology. He has over twenty-five years experience in human and experimental pathology as well as toxicology, preclinical drug safety evaluation and drug development. He advises both pharmaceutical companies and government in these areas.

PROFESSIONAL HISTORY:

CONSULTING PATHOLOGIST
March 2005 – present:
Advises on preclinical drug safety evaluation and toxicological pathology. Engaged in research in toxicological pathology, carcinogenesis and cancer chemoprevention. Member of the Committee on Carcinogenicity, United Kingdom

MEDICAL RESEARCH COUNCIL TOXICOLOGY UNIT, LEICESTER
Responsibility for the histopathological study of disease models and adverse hepatic effects of drugs in obesity in combination with genetic analysis, laser capture dissection microscopy, in situ hybridisation and immunocytochemistry.

ASTRAZENECA (FORMERLY ZENECA, ICI PHARMACEUTICALS), ALDERLEY PARK, CHESHIRE
March 1990 - February 2000: Head of Safety of Medicines Group
Responsibility for all preclinical safety studies and kinetics and metabolism work with approximately 300 staff in the UK and US in support of the discovery and development of novel drugs for all of ex-ZENECA Pharmaceuticals.

ZENECA (FORMERLY ICI) PHARMACEUTICALS, ALDERLEY PARK, CHESHIRE
January 1989 - February 1990: Head of Pathology
Responsibility for a group of 80 staff conducting histopathological evaluation of toxicity studies.

PARKE-DAVIS RESEARCH INSTITUTE, MISSISSAUGA, ONTARIO, CANADA
January 1987 - December 1988: Director of Research Institute
Responsibility for the Sheridan Park Research Laboratory (60 staff) undertaking preclinical safety studies for Parke-Davis Research centred at Ann Arbor, Michigan.

WELLCOME RESEARCH LABORATORIES, BECKENHAM, KENT, ENGLAND
January 1985 - December 1986: Head of Toxicology and Metabolism
Responsibility for drug safety evaluation, preclinical drug kinetics and radiochemistry at the Beckenham site (50 staff), in collaboration with Experimental Pathology and Toxicology at Research Triangle Park site.

CENTRE DE RECHERCHE, LABORATOIRES PFIZER, AMBOISE, FRANCE
September 1981 - December 1984: Director of Pathology
April 1979 - August 1981 - Pathologist
WESTMINSTER HOSPITAL MEDICAL SCHOOL & ST STEPHEN'S HOSPITAL, LONDON
September 1976 - March 1979 - Senior Registrar in Histopathology
February 1975 - February 1976 - Registrar in Histopathology

MEDIZINISCHE HOCHSCHULE, HANNOVER, GERMANY.
February 1976 - September 1976 - Assistant in Pathology

NEWCASTLE GENERAL HOSPITAL, NEWCASTLE-UPON-TYNE
September 1972 - February 1975 - Senior House Officer in Pathology

GRAVESEND HOSPITAL, KENT
October 1972 - May 1972 - House Physician

CHICHESTER HOSPITAL, WEST SUSSEX
February 1971 - August 1971 - House Surgeon

EDUCATION AND DEGREES:

* MBChB University of Birmingham, England, 1969
* MRCPath in human histopathology, Royal College of Pathologists, London, 1977
* FRCPath in histopathology & toxicology, Royal College of Pathologists, London, 1989
* GMC Registration in Morbid Anatomy and Histopathology under the European Specialist Medical Qualifications order 1995 (number 1491454)
* Medical Defence Union membership (membership number 095078D)

OTHER ACTIVITIES:

* Member of the Committee on Carcinogenicity, United Kingdom 2008-present
* Member of International Life Sciences Institute (ILSI) – Europe project on data selection for modelling of substances that are genotoxic and carcinogenic 2009-2011
* Chairman of International Harmonization of Nomenclature and Diagnostic Criteria committee for rodent soft tissue pathology 2009-present
* Member of the Veterinary Products Committee of the United Kingdom 2003-2007
* Member of the editorial board for Toxicologic Pathology 2002-2006
* Member of the editorial for board for Experimental & Toxicologic Pathology 2000-2007.
* Chairman of Zeneca Leisure 1996-1999: This group managed all the company leisure activities, clubs and leisure facilities, turnover £1 million per annum
* Member of Personnel steering group for Zeneca R&D in the UK 1996-1999
* Member of Health & Safety Steering Committee for the Alderley Park R&D site 1996-1999
* Biological Safety Officer, MRC Toxicology Unit 2000-2003

Date: 21 July 2010
PUBLICATIONS:

Books:


Main scientific papers:


Cancer Res. 62, 4256-4262.


Environ. Health Persp. 111, 847-853


Journal of Molecular Endocrinology 30, 1-11.


Toxicol. Pathol. 31, 263-272.


Cancer Res. 63, 5902-5908.


Journal of the American Society of Nephrology 14, 204A


Toxicol. Pathol. 32:22-25.


Int. J Cancer 111, 961-967.


Expt. Toxicol. Pathol. 56, 255-263.


Am. J Pathol, 166, 1041-1053.


prostate (TRAMP) tissue by $^1$H-NMR analysis—evidence for unusual phospholipid metabolism. *Prostate, 68*, 1035-1047.


[In Press withheld under Exemptions B4 and B6]
JERRY F. HARDISTY
CHIEF EXECUTIVE OFFICER/SENIOR PATHOLOGIST

EDUCATION:
Iowa State University, Pre-Veterinary, 1965-1967
Iowa State University, D.V.M., 1971
Certified by the American College of Veterinary Pathologists, 1976
Adjunct Associate Professor at the School of Veterinary Medicine, NC State University, 1983

PRESENT POSITION AND EXPERIENCE:
2010 - Present. Chief Executive Officer/Veterinary Pathologist, Experimental Pathology Laboratories, Inc., Research Triangle Park, North Carolina

Responsible for the overall implementation of the strategic goals and objectives of EPL. Provide leadership toward the company's philosophy, mission, strategy, and goals and objectives. Direct the company's business development and marketing efforts. Serve as the Principal Investigator as a Study Pathologist, Peer Review Pathologist and Chairperson for Pathology Working Groups and Scientific Advisory Panels.


Responsible for overall management and direction of contract research pathology laboratories in Virginia and North Carolina. The company serves both government and university research and the safety assessment programs of the pharmaceutical, chemical, and cosmetic industries.


Responsible for overall management and direction of pathology research laboratories in North Carolina and Virginia.


Responsible for the project management, direction and technical supervision of the North Carolina branch of EPL. Responsible for the microscopic evaluation of toxicological studies. Responsible for the National Toxicology Program's Pathology Quality Assessment Program and Operations of the NTP Archives.

1976 - 1978. Pathologist/Project Manager, Experimental Pathology Laboratories, Inc., Herndon, Virginia

Responsible for the management of EPL's Carcinogenesis Support Laboratory. Project Manager of a program to provide Tracor Jitco with Quality Assurance in the NCI Carcinogenesis Testing Program. Technical supervision of a program to provide pathology support services to the Carcinogenesis Program of the National Cancer Institute. Responsible for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies.
JERRY F. HARDISTY, DVM, DACVP

PRESENT POSITION AND EXPERIENCE – Continued
1972-1976 Research Pathologist, Veterinary Pathology Branch, Biomedical Laboratory, Edgewood Arsenal, Maryland

Dr. Hardisty was a preceptee in the U.S. Army preceptorship program in Veterinary Pathology. During this time he performed gross and microscopic diagnoses of spontaneous disease and changes produced by experimental procedures in laboratory animals. He prepared reports describing and interpreting these experimental results.

During this time he was principal investigator for the reproductive, mutagenic, teratogenic studies performed at the laboratory. This work consisted of revising previous experimental protocols and designing new experimental protocols to be utilized at the laboratory. The experimental design employed required the gross examination of pregnant female rats and fetuses for evidence of fetal toxicity and teratogenesis. He trained biological technicians to perform timed matings in rats, examine serially sectioned fetuses for malformations, and to examine fetal skeletons for prenatal abnormalities.

1971-1972 Attending Veterinarian, Division of BioSensor Research, Walter Reed Army Institute of Research

Dr. Hardisty studied the radiographic and morphologic lesions of several musculoskeletal diseases of the German Shepherd Dog. In association with Dr. Wayne Riser, he investigated the pathogenesis and possible genetic relationship of canine hip dysplasia, eosinophilic panosteitis and ununited anconeal processes in an attempt to reduce their incidence through a selective breeding program.

PROFESSIONAL MEMBERSHIPS:
Diplomate, American College of Veterinary Pathologists
ACVP Subspecialty in Toxicologic Pathology
American College of Toxicology
Society of Toxicology
Society of Toxicologic Pathologists
British Society of Toxicologic Pathologists
International Academy of Toxicologic Pathology
American Veterinary Medical Association
North Carolina Society of Toxicology
Charles Louis Davis, D.V.M. Foundation
The Society of Phi Zeta
The Society of Gamma Sigma Delta
The Fraternity of Alpha Zeta
The Fraternity of Omega Tau Sigma
American Association for the Advancement of Science
Standardized System of Nomenclature and Diagnostic Criteria (SSNDC), The
JERRY F. HARDISTY, DVM, DACVP

PROFESSIONAL ACTIVITIES – Continued
Joint Committee for STPs/ILSI on International Standardization of Nomenclature and Diagnostic Criteria for Toxicologic Pathology, 1994-1995, Co-Chairman 1995-Present.
Long Range Planning Committee, American College of Toxicology, 2002.
North American Director, International Academy of Toxicologic Pathology, 2002.

EDITORIAL REVIEW BOARD:
Editorial Board of Toxicologic Pathology, 2006-2008.

PUBLICATIONS AND PAPERS:
Defining a Noncarcinogenic Dose of Recombinant Human Parathyroid Hormone 1-84 in a 2-Year Study in Fischer 344 Rats. The Society of Toxicologic Pathology.
Factors predisposing to urolithiasis in feedlot cattle. Hardisty JF and Dillman RC. The Iowa State University Veterinarian, Iowa State University, Ames, Iowa, 33(2), 77-81, 1971.
JERRY F. HARDISTY, DVM, DACVP

PUBLICATIONS AND PAPERS – Continued
Evaluation of the effects of chemical compounds on the reproductive system of rats. Hardisty JF. Presented at the Biomedical Laboratory Review and Analysis, April 1975.

Reproductive studies with quint essence compounds. Hardisty JF, Presented at the Biomedical Laboratory Review and Analysis of Quint Essence, January 1976.


Neoplasms and pigmentation of the thyroid gland in F-344 rats exposed to 2,4-diaminoanisole sulfate, a hair dye component. Ward JM, Stinson, SF, Hardisty JF, Cockrell BY and Hayden DW. Journal of the National Cancer Institute, Vol. 62, No. 4, 1979. Apr;62(4) 1067-73


Cancer induction following single and multiple exposures to a constant amount of vinyl chloride monomer. Hehir RM, McNamara BP, McLaughlin J, Willigan DA, Bierbower G and Hardisty JF. Presented for the conference to re-evaluate the Toxicology of Vinyl Chloride Monomer, Polyvinyl Chloride and Structural Analogues on March 20-21, 1980, at the National Institute of Health, Bethesda, MD.

Cancer induction following single and multiple exposures to a constant amount of vinyl chloride monomer. Hehir RM, McNamara BP, McLaughlin J, Willigan DA, Bierbower G and Hardisty JF. Environmental Health Perspectives, 41, 63-72, October 1981.


JERRY F. HARDISTY, DVM, DACVP

PUBLICATIONS AND PAPERS – Continued


Systemic effects following inhalation of fog oil obscurant. Hardisty JF, Stead AG, Grose EC and Selgrade MJ. Presented at the North Carolina Chapter of the Society of Toxicology Meeting on February 2, 1985.


JERRY F. HARDISTY, DVM, DACVP

PUBLICATIONS AND PAPERS – Continued


Necropsy and histology in toxicologic pathology. Hardisty JF. Presented at Industrial Toxicologic Pathology, University of Illinois at Urbana-Champaign, July 27, 1994.


Pathology peer review and PWG. Hardisty JF. Presented at the 1995 Toxicology Roundtable in Nashville, TN on October 23, 1995


Peer review of histopathology data. Hardisty JF. Presented at the American College of Toxicology 17th Annual Meeting in King of Prussia, PA on November 11, 1996.

PUBLICATIONS AND PAPERS – Continued


Interaction of consultants, contract laboratories and industry-Panel Discussion with HE Black, AM Dahlem, JF Hardisty, TG Terrell. Presented at Industrial Toxicologic Pathology, University of Illinois at Urbana-Champaign, May 19, 1997.

Controversial issues in anatomic pathology. JF Hardisty. Presented at Industrial Toxicologic Pathology, University of Illinois at Urbana-Champaign, May 20, 1997.


Diagnostic dilemmas in toxicologic pathology. Hardisty Jerry. Presented at The 22nd Annual CL Davis DVM Foundation Continuing Education Symposium at North Carolina State University, College of Veterinary Medicine in Raleigh, North Carolina on June 14-18, 1998.


Controversial issues in anatomic pathology. Hardisty Jerry. Presented as a course entitled Industrial Toxicology and Pathology for the American Registry of Pathology at the Ramada Inn in Bethesda, MD on September 28, 1999.


Blind Pathology – When and When Not. Hardisty JF. Presented at the 51st Annual Toxicology Roundtable Program in Asheville, NC on October 15-18, 2000.


JERRY F. HARDISTY, DVM, DACVP

PUBLICATIONS AND PAPERS – Continued


Diagnostic dilemmas in toxicologic pathology. Presented at the 5th Industrial Toxicology and Pathology Course and symposium in Chicago, IL on July 9, 2002.

Histologic artifacts & diagnostic dilemmas. Presented at the RTP Rodent Pathology Course, Research Triangle Park, NC on September 8-10, 2002.


JERRY F. HARDISTY, DVM, DACVP

PUBLICATIONS AND PAPERS – Continued


The pathologist and pathology data. Hardisty JF. Presented at Health Canada in Ottawa, Canada on December 2, 2002.


Current approaches to Peer Review and PWG. Hardisty JF. Presented at Battelle in Columbus, OH on June 5, 2003.


ACT/STP Pathology Course for Non-Pathologists. Hardisty JF. Speaker at ACT/STP Meeting, Lincolnshire, IL, May 10-13, 2005.


Diagnostic Dilemmas in Toxicologic Pathology, Hardisty JF. Speaker, Presented at the 7th Biennial Industrial Toxicology & Pathology Short Course, Co-sponsored by the Society of Toxicologic Pathology and the University of Illinois College of Veterinary Medicine, July 23-25, 2007.


JERRY F. HARDISTY, DVM, DACVP

PUBLICATIONS AND PAPERS – Continued


Immunohistochemical Study of Brain Tumors in Rats Treated with Acrylonitrile. Kolenda-Roberts H, Hardisty JF. Poster Presentation at the Society of Toxicologic Pathology, Chicago, IL, July 20-24, 2010.

JERRY F. HARDISTY, D.V.M., DACVP

PUBLICATIONS AND PAPERS — Continued


PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P.
VETERINARY PATHOLOGIST

EDUCATION:
Washington University, St. Louis, Missouri, A.B., English Literature, 1966-1970
University of Missouri, St. Louis, Missouri, Pre-veterinary Studies, 1972-1974
University of Missouri, Columbia, Missouri, D.V.M., 1975-1979

CERTIFICATIONS/LICENSURE:
Certified by the American College of Veterinary Pathologists, 1984

PRESENT POSITION AND EXPERIENCE:
2007 – Present. Manager, EPL Northwest, Seattle, WA.

Responsible for project management and for the microscopic evaluation of
tissues from experimental animals used in a variety of toxicological studies from
pharmaceutical, biotechnical, and agricultural clients. Offering histopathology
and peer review services as well as organization of Pathology Working Groups.
Provide interpretation of ultrastructural pathology. Consultation to clients on
regulatory issues.


Responsible for project management and for the microscopic evaluation of
tissues from experimental animals used in a variety of toxicological studies from
pharmaceutical, biotechnical, and agricultural clients. Offering histopathology
and peer review services as well as organization of Pathology Working Groups.
Provide interpretation of ultrastructural pathology. Consultation to clients on
regulatory issues.

2000 – 2002. On-Site Consultant, DuPont Pharmaceuticals Company,
Wilmington, DE.

Full-time, on-site consultant to DuPont Pharmaceuticals Company. Provided
necropsy supervision and microscopic evaluation of tissues from experimental
animals used in a variety of toxicological studies by DuPont Pharmaceuticals
Company.
Experimental Pathology Laboratories, Inc.

PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED


Responsible for project management and for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies for both commercial clients and the National Toxicology Program’s Pathology Quality Assessment Program and the NTP Archives.


Responsible for project management, direction and technical supervision of the North Carolina Branch of EPL. Responsible for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies. Provided support to the National Toxicology Program’s Pathology Quality Assessment Program and the NTP Archives.


Duties included histopathologic interpretation of tissues from various laboratory animals used for toxicology and carcinogenesis studies.


1982 – 1985. Senior Lecturer, Department of Pathobiology, University of Pennsylvania School of Veterinary Medicine.

PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED


PROFESSIONAL MEMBERSHIPS:
American Veterinary Medical Association
American College of Veterinary Pathology
Society of Toxicological Pathology
British Society of Toxicologic Pathologists
C.L. Davis Foundation for the Advancement of Veterinary Pathology
North Carolina Society of Toxicology

SERVICE TO PROFESSIONAL ASSOCIATIONS:
Chairman, STP Nomenclature Subcommittee on the Mammary Gland

Member, STP Nomenclature Subcommittee on the Respiratory System
Adjunct Associate Professor at the School of Veterinary Medicine, NC State University, Department of Microbiology, Pathology and Parasitology
Member, STP Symposium Committee, 1995-1998
Co-Chairman, STP Educational Committee, 1996
Chairman, STP Symposium Committee, 1998
Copy Editor, C.L. Davis Foundation Newsletter, 1998
Member, Advisory Board, C.L. Davis Foundation for the Advancement of Veterinary Pathology, 2000-2004
Member, Executive Committee, Society of Toxicologic Pathology, 2000-2004
Chairman, STP Journal Committee, 2005
Chair, Global Editorial Steering Committee, 2006-2008
President-Elect, Society of Toxicologic Pathology, 2008-2009
President, Society of Toxicologic Pathology, 2009-2010
Member, ILSI/HESI Subcommittee on Distinguishing Adverse from Adaptive, Non-Functional, and Pharmacologic Changes in Toxicology Studies, 2009-2010

SERVICE TO EDITORIAL BOARDS OF SCHOLARY JOURNALS:
Reviewer for Toxicologic Pathology, 1998-2002
PROFESSIONAL DEVELOPMENT/SPECIALIZED TRAINING:

Educational Activities/Special Lectures:
1981 Diseases of zoo mammals and birds. Pathology of Laboratory Animals, Washington, D.C.

1982 Pathology of zoo animals. Friends of the National Zoo, Washington, D.C.

1982 Necropsy Service, University of Pennsylvania School of Veterinary Medicine, supervision of senior students and residents in small animal pathology rotation.

1982-1985 Necropsy Service, University of Pennsylvania School of Veterinary Medicine, supervision of senior students and residents in large animal pathology rotation.

1983 University of Pennsylvania School of Veterinary Medicine, Course 5402, Skin Diseases of Large Animals.


1983-1984 University of Pennsylvania School of Veterinary Medicine, Course 5001, General Endocrine Pathology.

1983 University of Pennsylvania School of Veterinary Medicine, Course 4501, Infectious Diseases of Dogs and Cats, Neuroendocrine Pathology.

1984 University of Pennsylvania School of Veterinary Medicine, Course 5401, Infectious Diseases of Dogs and Cats.

1984 University of Pennsylvania School of Veterinary Medicine, Course 5402, Skin Diseases of Large Animals, Diseases of Horses.

1985 University of Pennsylvania School of Veterinary Medicine, Course 5402, Diseases of Horses.

1996 School of Veterinary Medicine, NC State University, Department of Microbiology, Pathology and Parasitology, VMS 643: Toxicologic Pathology – Lymphoreticular.
1997  School of Veterinary Medicine, NC State University, Department of Microbiology, Pathology and Parasitology, VMS 643: Toxicologic Pathology – Lymphoreticular.

1999  Chemical Industry Institute of Toxicology, Pathology Short Course for Toxicologists. Necropsy and Histology Techniques. Pathology of genetically-engineered mouse lines used in new short-term carcinogenesis bioassays.

2002  Society of Toxicology, Continuing Education Course: Blood and Lymphoid Tissue: Neoplasia of Blood and Lymphoid Tissue.

2003  Society of Toxicology, Continuing Education Course: Integrating Toxicologic Pathology into Compound Evaluation and Risk Assessment II: Diagnostic Drift.

2006  International Institute of Biotechnology and Toxicology, Chennai, Tamil Nadu, India: Regulatory Toxicologic Pathology

2007  School of Veterinary Medicine, Purdue University. Laboratory Animal Medicine The Use of Genetically-Modified-Mice in Toxicology


2010  School of Veterinary Medicine, Purdue University. Laboratory Animal Medicine, The Use of Genetically-Modified-Mice In Toxicology and Trust me, I'm a Pathologist.

National Institute for the Control of Pharmaceuticals and Biological Products and the Society of Toxicologic Pathology: USA-China Carcinogenicity Studies Workshop, Beijing, China. Reading the Rodent Bioassay: Problems, Pitfalls and Peer Review and Common Background Tumors of Laboratory Rodents.
Seminars and Presentations:

Canine parvovirus. Johns Hopkins Division of Comparative Medicine, Baltimore, 1980.


Leiomyomas of the genital tract in large zoo mammals. International Academy of Pathology, Chicago, 1981.

Respiratory distress syndrome in neonatal reindeer (poster). International Academy of Pathology, Chicago, 1981.

Herpesvirus infections in old world primates. Johns Hopkins Division of Comparative Medicine, Baltimore, 1981.

Selected diseases of zoo animals. University of Pennsylvania School of Veterinary Medicine, Philadelphia, 1981.

Tuberculous osteomyelitis in captive marsupials (poster). International Academy of Pathology, Boston, 1982.

Selected diseases of zoo animals. Virginia-Maryland Regional College of Veterinary Medicine, Blacksburg, 1982.


Lesions of Dioxin in laboratory animals. Society of Toxicologic Pathologists 15th International Symposium, St. Louis, Missouri, 1996.
Use of genetically altered mice in short-term bioassays. The 22nd Annual C.L. Davis DVM Foundation Continuing Education Symposium, North Carolina State University, College of Veterinary Medicine, Raleigh, North Carolina, June 14-18, 1998.


Pathology of genetically-engineered mouse lines used in new short-term carcinogenesis bioassays. CL Davis Foundation European Pathology Division Symposium, Nantes, France, July 1999.


Background pathology of genetically-engineered mouse lines and the significance of strain variability. Pathology of Mutant Animal Models, sponsored by the CL Davis Foundation, Houston, TX, February 17-19, 2000.


Background pathology of genetically-engineered mouse lines and the significance of strain variability. Pathology of Mutant Animal Models sponsored by the CL Davis Foundation, Houston, TX, February 15-17, 2001.

Pathology of Transgenic Mice. CL Davis Foundation European Division Pathology Symposium (Szent Istvan University, Budapest, Hungary), July 5-7, 2001.


Pathology Data and Tox-Path Issues. USFDA, May 20, 2002.


Diagnostic Dilemmas. Industrial and Toxicologic Pathology Course VI. Chicago, IL, July 18-21, 2004.

Pathology of p53 heterozygous Transgenic Mice, CL Davis Foundation, Northeast Division Meeting, December 10, 2004, Nutley NJ.


The PTOX Seminar Series: Transgenic Models. Forest Research Institute, October 21, 2004, Jersey City, NJ.

An Introduction to Toxicologic Pathology, Adolor Corporation, March 4, 2005, Exton, PA.

Adverse vs Non-Adverse Lesions in Toxicology Studies. Korean Institute of Toxicology, June 1, 2005, Daejong, South Korea.


Transgenic Mice: Creation, Pathology and Use in Toxicology Studies. CL Davis Foundation European Division; Annual Meeting, September 6, 2005, Naples, Italy.

The Rodent Biossay in the 21st Century: Reading the Study – Problems, Pitfalls and Peer Review. CL Davis Foundation, NorthEast Division, November 11, 2005, Nutley, NJ.

INHAND and the GESC – the New Nomenclature Project. Japanese Society of Toxicologic Pathology, February 7, 2008, Nagoya, Japan
PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

Pathology of Transgenic Mice. DIMS Institute of Medical Science, February 8, 2008, Ichinomiya, Japan

Trust Me, I’m a Pathologist. American College of Toxicology, Palm Springs, November 1, 2009, Palm Springs, CA.

PUBLICATIONS AND PRESENTATIONS:

Books:

Book Chapters:


Principles of Pathology for Toxicology Studies by Steven R. Frame and Peter C. Mann. In; Principles and Methods of Toxicology, Fifth Edition (A. Wallace Hayes, ed), Boca Raton, FL, CRC Press, 2008

Abstracts:


Mann, P.C., Montali, R.J. and Bush, M.: Tuberculous osteomyelitis in captive marsupials. Laboratory Investigation, 1982, 46-51A.


Acute Adverse Effects of the Indenopyridine, CDB-4022 (Racemate), on the Ultrastructure of Sertoli Cells, Spermatocytes, and Spermatids in the Testes of Treated Rats: Comparison to the Known Sertoli Cell Toxicant, Di-n-Pentylphthalate (DPP), 38th Annual Meeting, Society for the Study of Reproduction, July 24-27, 2005, Quebec City, Quebec, Canada.

Scientific Papers:


[Redacted]

PETER C. MANN, D.V.M.
Diplomate, A.C.V.P.

APRIL 23, 2018
Date
JAMES B. NOLD

Biotechnics

Formal Education:

1985 Colorado State University
Fort Collins, CO
PhD Pathology

1980 The Armed Forces Institute of Pathology
Washington, DC
Pathology Residency Diploma

1973 Ohio State University
Columbus, OH
DVM

Board Certifications and Licensure:

Diplomate, American College of Veterinary Pathologists, 1980

Professional Experience:

WIL Research Laboratories, LLC/Biotechnics
Hillsborough, NC

02/09/09 - Present Position: Senior Pathologist
Pathology

Performs microscopic examination of material obtained from various in-house studies utilizing different species. These will include acute, subacute and chronic studies. Records the microscopic findings in the on-line computer system utilizing the pathology master list of terms or microscopic lesions established for the given species or organ. Correlates the clinical pathology data with the microscopic observations. Writes the pathology summary, which includes organ weight, gross, microscopic and clinical pathology interpretations on various studies. Provides consultation to the necropsy group during the examination of individual animals sacrificed or which died on study. Provides direction and professional consultation for the department during the absence of the Director. Scientific and technical adviser for necropsy and histology labs. Maintains professional level of expertise by attending scientific meetings,
Professional Experience (Continued):

reading appropriate professional journals, and participating in professional organizations. Special interests in neuropathology include brain morphometry in developmental toxicity studies. Assists with the clinical care of study animals.

GlaxoSmithKline
Research Triangle Park, NC

2003 - 2009  Position:  Director of Morphologic Pathology
              Safety Assessment, Pathology

  Directed the histology and necropsy service function and supervised the Manager of Necropsy and Laboratory Services. Managed the contracted histopathology workload and assisted in scheduling and assignment of studies. Provided pathology support to both research and development functions, including consultation and collaboration on target and chemical class liability, animal model selection, and investigative and regulatory study design, as well as gross, microscopic and molecular pathologic evaluation and data interpretation of target localization and biological profiling, investigational, and regulatory studies.

2001 - 2003  Position:  Director of Regulatory & Discovery Pathology
              Safety Assessment, Pathology

  Provided pathology support to both research and development functions, including consultation and collaboration on target and chemical class liability, animal model selection, and investigative and regulatory study design, as well as gross, microscopic and molecular pathologic evaluation and data interpretation of target localization and biological profiling, investigational, and regulatory studies.

Pathology Associates
A Charles River Company
Durham, NC

1997 - 2001  Position:  Division Director

  Was responsible for the overall operation of the North Carolina Division for Pathology Associates – A Charles River Company. Served as the senior administrator of the group and directly
supervises five doctorate level scientists and the Division Director. Served as a study pathologist and as a business development representative for the organization. Specialized in general toxicologic pathology and electron microscopy. The North Carolina Division currently has a staff of 20 personnel.

Covance Laboratories, Inc.
Pathology Department
Madison, WI

1993 – 1996

**Position:** Director of Pathology

Responsible for all administrative functions of the department and for the scientific direction of the Anatomical Pathology Section (which includes necropsy and histology) and the Clinical Pathology Section (which includes hematology and clinical chemistry). Directly supervised five anatomical pathologists, one clinical pathologist, the section supervisors of the Anatomic Pathology Section, and an administrative assistant. Also served as a study pathologist. Special interests in morphometry, immunopathology, and general toxicologic pathology.

Corning Hazleton, Inc.
Pathology Department
Madison, WI

1990 - 1993

**Position:** Pathologist

Study pathologist for acute, subchronic, chronic, and reproductive toxicology, and oncogenicity studies using rats, mice, dogs, rabbits, nonhuman primates, and domestic livestock as the experimental animals. Supervised the macroscopic examination of the test animals, evaluated the prepared tissues, and wrote the pathology portion of the study reports.

Specialized in morphometry and immunohistochemistry techniques. Radiation pathology, immunopathology, and acute toxicologic pathology were particular areas of interest.
Articles:


**Articles (Continued):**


Nold, J.B.; Benjamin, S.A.; Miller, G.H. Radiation injury to the canine thymus and Lymphohematopoietic stem cells: correlation with functional immunological deficits, DNA-TR-86-207, Defense Nuclear Agency, Armed Forces Radiobiology Research Institute, Bethesda, Maryland, **1986**.


Cockerham, L.G.; Doyle, T.F.; Trumbo, R.B.; Nold, J.B. Acute post-irradiation canine


**Articles (Continued):**


**Books:**


**Abstracts:**


Abstracts (Continued):


Abstracts (Continued):


Miller, G.K.; Nold, J.B.; Benjamin, S.A. Prenatal and neonatal radiation injury and immunologic development. Laboratory Investigation 1986, 54, 43A.
ROBERT R. MARONPOT
SENIOR PATHOLOGIST

EDUCATION:
Michigan State University, B.S., 1963
Michigan State University, D.V.M., 1965
Michigan State University, M.S., 1966
Harvard University, M.P.H., 1972

PRESENT POSITION AND BACKGROUND:
2008 – Present
Senior Pathologist, Experimental Pathology Laboratories, Inc.
Research Triangle Park, NC

2007 – Present
Maronpot Consulting, LLC, 1612 Medfield Road
Raleigh, NC

1992 - 2006
Chief, Laboratory of Experimental Pathology, Environmental Toxicology Program, National Institute of Environmental Health Sciences, Research Triangle Park, NC

1991 - 1992
Chief, Experimental Toxicology Branch, National Toxicology Program
National Institute of Environmental Health Sciences, Research Triangle Park, NC

1990 - 1991
Head, Cancer Genetics & Molecular Pathology, Experimental Carcinogenesis & Mutagenesis Branch, National Institute of Environmental Health Sciences, Research Triangle Park, NC

1989 - 1993
Board of Directors, American Board of Toxicology, Washington, D.C.
University of North Carolina, Chapel Hill, N.C.

1981 - 1990
Head, Experimental Pathology, Chemical Pathology Branch, National Toxicology Program, National Institute of Environmental Health Sciences, Research Triangle Park, NC

1978 - 1981
Senior Fellow, Bushy Run Research Center, Carnegie-Mellon University
4400 Fifth Avenue, Pittsburgh, Pennsylvania

1975 - 1978
Head, Pathology Department, Chemical Hygiene Fellowship, Carnegie-Mellon Institute of Research, 4400 Fifth Avenue, Pittsburgh, Pennsylvania

1974 - 1975
Head, Research Animal Facility

1974 - 1975
Acting Head, Experimental Pathology Division, Naylor Dana Institute for Disease Prevention, American Health Foundation, Valhalla, New York
ROBERT R. MARONPOT, DVM, MS, MPH

PRESENT POSITION AND BACKGROUND: – Continued
1974 - 1975 Clinical Assistant Professor of Pathology, New York Medical College, Valhalla, New York
1975 Consultant in Veterinary Pathology, Memorial Sloan-Kettering Cancer Research Center, New York, New York
1972 - 1974 Research Fellow in Comparative Pathology, Pathology Department, Harvard Medical School and Angell Memorial Animal Hospital, Boston, Massachusetts
1971 - 1972 Research Fellow in Public Health, Microbiology Department, Harvard School of Public Health, Boston Massachusetts, Valhalla, New York
1968 - 1971 Head, Veterinary Medicine Department, U.S. Naval Medical Research Unit #3, Cairo, Egypt
1966 - 1968 Veterinary Laboratory Officer, Veterinary Corps, U.S. Army Pathology Division, U.S. Army Medical Research and Nutrition Laboratory, Denver, Colorado
1965 - 1966 NIH Postdoctoral Fellow, Pathology Department, Michigan State University, East Lansing, Michigan

PROFESSIONAL MEMBERSHIPS:
American College of Veterinary Pathologists
Society of Toxicologic Pathologists
Society of Toxicology

SPECIALTY BOARDS & HONORS:
Diplomate, American College of Veterinary Pathologists, 1973
Diplomate, American Board of Toxicology, 1980
Distinguished Postdoctoral Veterinary Alumnus Award from Michigan State University College of Veterinary Medicine - 2000
President, Society of Toxicologic Pathology - 2001-2002
Editor-in-Chief, Toxicologic Pathology – 2001-2004
SELECTED NATIONAL & INTERNATIONAL INVITED PRESENTATIONS SINCE 2007:

2007 Lectures
- Society of Toxicology Annual Meeting
  Charlotte, NC – March 2007
  Lectured at a Continuing Education Course
  Rodent Imaging Overview for the Toxicologist
  “Magnetic Resonance Imaging”

- 7th Biennial Industrial Toxicology & Pathology Short Course
  University of Illinois – July 2007
  “Carcinogenicity Assessment”
  and
  “Application of Multimodality Imaging in Toxicologic Pathology”

- American Association for Laboratory Animal Science Annual Meeting
  Charlotte, NC – October 2007
  The Wallace P. Rowe Lecture
  “The Cancer Bioassay: Challenges for the Future”
  and
  Seminar on Current Imaging Modalities for Rodent Xenograft Models
  “MRI Imaging Systems”

- National Academy of Science Workshop on Mouse Liver Tumors
  Washington, DC – November 2007
  “Mouse Models for Carcinogenicity”

- American College of Veterinary Pathologists
  Savannah, Georgia – November 2007
  Lectured at a Continuing Education Course
  Rodent Imaging Overview for the Pathologist
  “Magnetic Resonance Imaging”

2008 Lectures
- ILSI Annual Meeting
  Organized symposium on “Applications of Small Animal Imaging in Toxicology
  Research and Testing”
  Lectured on “Application of Magnetic Resonance Imaging in Toxicology and
  Toxicologic Pathology”

- NIEHS
  February 2008
  Lecture on “Comparative Medicine Branch Pathology/Case Presentations”

- Aperio Research Triangle Park Digital Pathology Seminar
  May 13, 2008
  Lecture on “Digital Pathology for Peer Review and Phenotyping”
ROBERT R. MARONPOT, DVM, MS, MPH

SELECTED NATIONAL & INTERNATIONAL INVITED PRESENTATIONS SINCE 2007: Continued

• NTP Satellite Symposium, STP Annual meeting
  Conundrums in Toxicologic Pathology
  June 21, 2008, San Francisco

• 2nd East Mediterranean ICLAS Regional Meeting
  “Overview of Imaging Modalities and Control of Small Animal Physiology During Live Imaging” and “Application of MRI in Toxicology and Toxicologic Pathology”
  Jerusalem, Israel, December 3-4, 2008.

• TEVA Pharmaceutical Company, Israel
  “The Cancer Bioassay: Past, Present, Future”
  December 8, 2008

EDITORIAL REVIEW BOARD:
Editor – Toxicologic Pathology (2001-2004)
Editorial Board – Toxicologic Pathology (1986-2001)
Section Editor, Laboratory Animal Pathology (1996-2001)
Editorial Board – Drug and Chemical Toxicology (1986-1992)
Senior Advisor – Toxicologic Pathology (2005-present)
Editorial Board – Experimental & Toxicologic Pathology (2001-present)

EDITORIAL ACTIVITIES:
Ad hoc Reviewer
Comparative Medicine
Carcinogenesis
Molecular Carcinogenesis
Cancer
International Journal of Cancer
Toxicological Sciences
Cancer Research
American Journal of Pathology
Proceedings of the National Academy of Sciences (USA)
American Journal of Respiratory Cell & Molecular Biology
Food and Chemical Toxicology
ROBERT R. MARONPOT, DVM, MS, MPH

PUBLICATIONS AND PAPERS:


ROBERT R. MARONPOT, DVM, MS, MPH

PUBLICATIONS AND PAPERS: – Continued


ROBERT R. MARONPOT, DVM, MS, MPH

PUBLICATIONS AND PAPERS: – Continued


ROBERT R. MARONPOT, DVM, MS, MPH

PUBLICATIONS AND PAPERS: – Continued


PUBLICATIONS AND PAPERS: – Continued


ROBERT R. MARONPOT, DVM, MS, MPH

PUBLICATIONS AND PAPERS: – Continued


ROBERT R. MARONPOT, DVM, MS, MPH

PUBLICATIONS AND PAPERS: – Continued


ROBERT R. MARONPOT, DVM, MS, MPH

PUBLICATIONS AND PAPERS: – Continued


PuBlicAtiOns AnD PaPerS: – ContiNued

Goodrow T, Reynolds S, Maronpot R, and Anderson M, 1990. Activation of K-ras by Codon 13 Mutations in C57BL/6 x C3H F1 Mouse Tumors Induced by Exposure to 1,3-butadiene. Cancer Res. 50: 4818-4823.


ROBERT R. MARONPOT, DVM, MS, MPH

PUBLICATIONS AND PAPERS: – Continued


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PUBLICATIONS AND PAPERS: – Continued


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PUBLICATIONS AND PAPERS: – Continued


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PUBLICATIONS AND PAPERS: – Continued


PUBLICATIONS AND PAPERS: -- Continued


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PUBLICATIONS AND PAPERS: – Continued


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PUBLICATIONS AND PAPERS: – Continued


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PUBLICATIONS AND PAPERS: – Continued


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PUBLICATIONS AND PAPERS: – Continued


PUBLICATIONS AND PAPERS: – Continued


BOOK CHAPTERS/FASCICLES:


ROBERT R. MARONPOT, DVM, MS, MPH

BOOK CHAPTERS/FASCICLES: – Continued


ROBERT R. MARONPOT, DVM, MS, MPH

BOOK CHAPTERS/FASCICLES: – Continued


CO-EDITED SYMPOSIA PROCEEDINGS:


ROBERT R. MARONPOT, DVM, MS, MPH

EDITED BOOKS:


EDITED MONOGRAPHS: