# Cleaning Memos Title List

This list contains all the titles through 2019. It will be updated with 2020 titles in December 2020. It is included for those who might want to browse by title. This does not include links to the specific Cleaning Memos. To view those, you must go the Memos dropdown menu and select the year you want to view.

<table>
<thead>
<tr>
<th>Date</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2019</strong></td>
<td></td>
</tr>
<tr>
<td>December</td>
<td>Issues in Rinsing - Part 2</td>
</tr>
<tr>
<td>November</td>
<td>Issues in Rinsing - Part 1</td>
</tr>
<tr>
<td>October</td>
<td>Limits for &quot;Product A to Product A&quot;</td>
</tr>
<tr>
<td>September</td>
<td>Cleaning Validation for Homeopathic Drug Products</td>
</tr>
<tr>
<td>August</td>
<td>What’s a Visual Limit?</td>
</tr>
<tr>
<td>July</td>
<td>Use of the Terms Grouping and Matrixing</td>
</tr>
<tr>
<td>June</td>
<td>Deviations and Nonconformances</td>
</tr>
<tr>
<td>May</td>
<td>Use of the Term &quot;Product&quot;</td>
</tr>
<tr>
<td>April</td>
<td>Surfaces Areas in Carryover Calculations</td>
</tr>
<tr>
<td>March</td>
<td>Contaminants in API Manufacture</td>
</tr>
<tr>
<td>February</td>
<td>Significant Figures: Back to Basics</td>
</tr>
<tr>
<td>January</td>
<td>The Value of a Protocol Worksheet for Manual Cleaning</td>
</tr>
<tr>
<td><strong>2018</strong></td>
<td></td>
</tr>
<tr>
<td>December</td>
<td>Clarifying Terms: Blanks vs. Controls</td>
</tr>
<tr>
<td>November</td>
<td>More Swab Sampling Issues</td>
</tr>
<tr>
<td>October</td>
<td>Timing for Swab Sampling in a Protocol?</td>
</tr>
<tr>
<td>September</td>
<td>What If the Next Product is the Same Product?</td>
</tr>
<tr>
<td>August</td>
<td>Other Issues in EMA’s Q&amp;A</td>
</tr>
<tr>
<td>July</td>
<td>The EMA Q&amp;A on Routine Analytical Testing</td>
</tr>
<tr>
<td>June</td>
<td>The EMA Q&amp;A &quot;Clarification&quot; on Limits</td>
</tr>
<tr>
<td>May</td>
<td>&quot;Concurrent Release&quot; for Cleaning Validation</td>
</tr>
<tr>
<td>April</td>
<td>Dealing with Used and New Equipment</td>
</tr>
<tr>
<td>March</td>
<td>Carryover Calculation Errors to Avoid</td>
</tr>
<tr>
<td>February</td>
<td>Does a High &quot;Margin of Safety&quot; Protect Patients?</td>
</tr>
<tr>
<td>January</td>
<td>A Look at the Revised Risk-MaPP</td>
</tr>
<tr>
<td><strong>2017</strong></td>
<td></td>
</tr>
<tr>
<td>December</td>
<td>What’s at Stake with HBELs</td>
</tr>
<tr>
<td>November</td>
<td>Toxicity as a Worst-Case Grouping Factor</td>
</tr>
<tr>
<td>October</td>
<td>Meaning of “Dedicated”?</td>
</tr>
<tr>
<td>September</td>
<td>Another Issue for API Synthesis</td>
</tr>
<tr>
<td>August</td>
<td>EMA’s Q&amp;A Clarification: Part 2</td>
</tr>
<tr>
<td>July</td>
<td>EMA’s Q&amp;A Clarification: Part 1</td>
</tr>
<tr>
<td>June</td>
<td>Pass/Fail Analytical Test Methods</td>
</tr>
<tr>
<td>May</td>
<td>Issues in Product Grouping</td>
</tr>
<tr>
<td>April</td>
<td>Dirty and Clean Hold Time Protocols</td>
</tr>
<tr>
<td>March</td>
<td>Establishing Clearance for Degraded Protein Actives</td>
</tr>
<tr>
<td>February</td>
<td>A Possible Approach for Biotech Limits</td>
</tr>
<tr>
<td>January</td>
<td>A Critique of the APIC Guideline</td>
</tr>
</tbody>
</table>
2016
December  Limits for Batch Splitting - Part 2
November  Limits for Batch Splitting - Part 1
October   Limits for Products with Multiple Actives
September What is Placebo Cleaning?
August    What is Placebo Sampling?
July      Should 10 PPM be Used for Limits?
June      Limits for Small Molecule API Synthesis - Part 3
May       Limits for Small Molecule API Synthesis - Part 2
April     Limits for Small Molecule API Synthesis - Part 1
March     Meeting EMA Requirements for Existing Products
February  Understanding Sources of Variation in Validation Protocols
January   Understanding Sources of Variation in Cleaning Process

2015
December  Special Cases in Determining “Visually Clean”
November  Only Read This If Applicable
October   Comparing Swab and Rinse Results
September Duration Specific Health-based Limit Values
August    Route Specific Health-based Limit Values
July      Significance of GRAS
June      What’s in Annex 15?
May       EMA on Limits for Shared Facilities – Part 3
April     EMA on Limits for Shared Facilities – Part 2
March     EMA on Limits for Shared Facilities – Part 1
February  What’s a Potent Active
January   Regulatory Status of “Visually Clean Alone”

2014
December  Is Pre-cleaning Allowed?
November  White Rings in Buffer Tanks
October   Cleaning Validation Limits for Lyophilizers – Part 3
September Cleaning Validation Limits for Lyophilizers – Part 2
August    Cleaning Validation Limits for Lyophilizers – Part 1
July      Dealing with Preferential Transfer of Residues
June      Issues in Equipment Grouping
May-Addendum Shortcomings of ADE/PDE Values for Cleaning Validation
May       Sampling Recovery for Volatile Materials
April     Cleaning Validation for Continuous Manufacture
March     Test Until Clean?
February  Mock Soils and Mock Soiling
January   Setting Limits for Cleaning Agents

2013
December  A Way Forward for “Health-based” Limits
November  Comments on the EMA Guideline on Dedicated Facilities
October   Revisiting Rinse Sampling Recovery Studies
September Revisiting Linearity of Recovery Studies
August    Conductivity vs. pH vs. TOC for Final Rinse Monitoring: Part 2
July      Conductivity vs. pH vs. TOC for Final Rinse Monitoring: Part 1
June      Are Health-Based Limits Enough?

Cleaning Memos Title List 2000-2019
2012
December  Grouping for Surfaces for Swab Recovery Studies?
November  Selecting the Number of Validation Runs for Equipment Grouping
October Addendum  Another Critique of Risk-MaPP
October  Revisiting Limits Based on Process Capability
September  My Revised Shorthand for Expressing Limits
August  Differences between Cleaning and Process Validation
July  Significance of Water Activity for Cleaning Validation
June  Regulatory Guidances I’d Like to See Changed – Part 2
May  Regulatory Guidances I’d Like to See Changed – Part 1
April  How to Completely Avoid Doing Cleaning Validation
March  How Are ADE’s Determined for Non-Highly Hazardous Actives?
February  Hold Time Issues
January  Issues in Cleaning Validation for Parts Washers

2011
December  The Good, the Bad and the Inexplicable of Risk-MaPP
November  Limits Below the LOD in Rinse Solutions – Part III
October  Limits Below the LOD in Rinse Solutions – Part II
September  Limits Below the LOD in Rinse Solutions – Part I
August  More on an Alternative Swab Recovery Procedure
July  Manual Cleaning Issues – Part 2
June Addendum  Where Risk-MaPP Got It Wrong
June  Manual Cleaning Issues – Part 1
May  An Alternative Swab Recovery Procedure
April  A Conundrum Regarding Limits
March  What Does the FDA Process Validation Guidance Say about the Number of Qualification Runs
February  More on ISPE’s Risk-MaPP
January  More on Campaign Length

2010
December  Understanding the Cleaning Process in 2010 (and Beyond)
November  A Critique of Cleaning Validation Issues in ISPE’s Risk-MaPP
October  Swab Sampling Recovery as a Function of Residue Level
September  More Uses for Visual Limit Determination
August  Visually Clean and Visual Limits
July  Statistics for Visual Limits
June  Acceptable Variability for Sampling Recovery Studies
May  Final Notes on “Stratified Sampling”
April  More on “Stratified Sampling”
March  Basics of “Stratified Sampling”
February  Revisiting “Cleaning Verification”
January  What’s an “Equivalent” Swab?
2009
December The Rationale for Rinse Sampling for Cleaning Agents
November “Continued” vs. “Continuous” Process Verification
October Use of Multiple Swabs for Sampling
September “Design Space” for Cleaning Processes
August The Changing Paradigm for Cleaning Validations
July Revisiting Linearity of Swab Recovery Results
June Use of Alkali/Acid Cleaning Agents in Biotech
May The Science Behind Limits
April What’s Happening to Worst-case Process Conditions?
March Differing Ways to Express Limits
February Another Alternative for Rinse Sampling Limits
January Limits for Rinse “Grab” Samples

2008
December Solvent Reflux Sampling Recovery
November Limits for Topicals
October Are We Setting Limits Correctly?
September Sampling Recovery for Biotech
August Do Three Verifications Make a Validation?
July What’s Happening to Revalidation?
June Still More on Floors and Walls
May More on Floors and Walls
April What Have We Learned in the Last Two Decades?
March Canada’s Revised Guidelines
February A Stroll Down Memory Lane
January Can Protocols Use Limit Tests?

2007
December More on Limits for API Manufacture
November Measuring Residues of Volatile Solvents?
October Downsides to TOC?
September TOC Analytical Method Validation
August Master Plans vs. Policies
July Spiking Amounts for Sampling Recovery Studies
June Issues in Campaigns
May Revisiting Medically Safe Limits
April Limits for Bulk Biotech Manufacture – Part 2
March Limits for Bulk Biotech Manufacture – Part 1
February Microbiological Test Method Validation?
January Dealing with Deviations in the CEHT

2006
December Dealing with Deviations in the DEHT
November Use of Sampling Templates
October CV for General Room Surfaces?
September CEHT for Sterilized Equipment
August Surface Roughness and Cleaning
July FTIR with Fiberoptic Sampling
June Ion Mobility Spectrometry
May Measuring Bioburden in Protocols
April More on Using Rinse Sampling Alone
March Separating CEHT Protocols from Cleaning Protocols

Cleaning Memos Title List 2000-2019
### 2005

**February**
- Bioburden Proliferation in CEHT Protocols

**January**
- Acceptance Criteria for Dedicated Equipment

**December**
- Selecting the Swab Sampling Area

**November**
- Averaging Swab Sample Results?

**October**
- Limits for Rinse “Grab” Samples

**September**
- More on Limits for Formulated Cleaning Agents

**August**
- Issues in Limits for Formulated Cleaning Agents

**July**
- Revisiting Cleaning Validation for Medical Devices

**June**
- Setting Limits Based on Process Capability?

**May**
- Objectionable Microorganism Concept in Cleaning Validation

**April**
- Cleaning Validation for Packaging Equipment: Part 2

**March**
- Cleaning Validation for Packaging Equipment: Part 1

**February**
- Dealing with Unknown Peaks

**January**
- Understanding the Cleaning Process

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### 2004

**December**
- Establishing Adequate Solubility for TOC Analysis

**November**
- Is Rinse Sampling Alone Acceptable?

**October**
- Selecting Worst-Case Products for Grouping

**September**
- Issues in the Visual Examination of Equipment Surfaces

**August**
- More on Specificity of Analytical Methods

**July**
- Cleaning After a Media Fill

**June**
- TOC Issues: Part 3 – Blanks for Recovery Studies

**May**
- TOC Issues: Part 2 - Appropriate Blanks

**April**
- TOC Issues: Part 1 - Sampling Materials

**March**
- Defining Three “Consecutive” Runs

**February**
- Endotoxin Issues in Cleaning Validation

**January**
- Monitoring a Validated Cleaning Process

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### 2003

**December**
- Revalidation

**November**
- Correlation of TOC with a Specific Analytical Method?

**October**
- PAT and Cleaning Validation

**September**
- Correlation of Swab and Rinse Sample Results?

**August**
- Why TOC is Acceptable

**July**
- Adequate “Documented Evidence” for Cleaning Validation

**June**
- Limits for Drugs with Multiple Actives

**May**
- What’s Really Different About Biotech?

**April**
- Using Statistics in Sampling?

**March**
- Is a Dirty Swab a “Visually Clean” Failure?

**February**
- Using Sampling Recovery Percentages

**January**
- More on DEHT Issues

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### 2002

**December**
- Additional Considerations in Recovery Studies Part 2

**November**
- Additional Considerations in Recovery Studies Part 1

**October**
- Recovery Studies for Rinse Sampling

**September**
- Sampling the Sampling Rinse

**August**
- Selecting Swab Sampling Sites

**July**
- Worst-case Process Conditions

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Cleaning Memos Title List 2000-2019
<table>
<thead>
<tr>
<th>Month</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>June</td>
<td>Recovery Studies for Microbial Sampling?</td>
</tr>
<tr>
<td>May</td>
<td>Cleaning Validation for Medical Devices</td>
</tr>
<tr>
<td>April</td>
<td>Understanding and Applying “Visually Clean”</td>
</tr>
<tr>
<td>March</td>
<td>What’s a Contaminant?</td>
</tr>
<tr>
<td>February</td>
<td>The Use of Default Limits</td>
</tr>
<tr>
<td>January</td>
<td>The Use of Safety Factors in Limits Calculations</td>
</tr>
<tr>
<td>2001</td>
<td></td>
</tr>
<tr>
<td>December</td>
<td>What’s a “Dose” for Calculating Limits?</td>
</tr>
<tr>
<td>November</td>
<td>Cleaned Equipment Hold Time</td>
</tr>
<tr>
<td>October</td>
<td>Dirty Equipment Hold Times</td>
</tr>
<tr>
<td>September</td>
<td>Handling Sampling Recovery Results</td>
</tr>
<tr>
<td>August</td>
<td>Equipment Grouping Strategies for Cleaning Validation</td>
</tr>
<tr>
<td>July</td>
<td>Product Grouping Strategies for Cleaning Validation</td>
</tr>
<tr>
<td>June</td>
<td>Water Quality for Validated Cleaning Processes</td>
</tr>
<tr>
<td>May</td>
<td>Setting “Dose” Limits without Dosing Information</td>
</tr>
<tr>
<td>April</td>
<td>Cleaning for Manufacture of Clinical Trial Materials (CTMs)</td>
</tr>
<tr>
<td>March</td>
<td>The New FDA Compliance Program Guidance Manual and Cleaning Validation</td>
</tr>
<tr>
<td>February</td>
<td>Validation of Analytical Methods</td>
</tr>
<tr>
<td>January</td>
<td>Specificity of Analytical Methods</td>
</tr>
<tr>
<td>2000</td>
<td></td>
</tr>
<tr>
<td>November</td>
<td>Campaigns and Dedicated Equipment</td>
</tr>
<tr>
<td>October</td>
<td>The Applicability of Cleaning Validation</td>
</tr>
</tbody>
</table>