Cleaning Memos Title List

This list contains all the titles through 2018. It will be updated with 2019 titles in November 2019. 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.

Date	Title
2018	
December	Clarifying Terms: Blanks vs. Controls
November	More Swab Sampling Issues
October	Timing for Swab Sampling in a Protocol?
September	What If the Next Product is the Same Product?
August	Other Issues in EMA's Q&A
July	The EMA Q&A on Routine Analytical Testing
June	The EMA Q&A "Clarification" on Limits
May	"Concurrent Release" for Cleaning Validation
April	Dealing with Used and New Equipment
March	Carryover Calculation Errors to Avoid
February	Does a High "Margin of Safety" Protect Patients?
January	A Look at the Revised Risk-MaPP
2017	
December	What's at Stake with HBELs
November	Toxicity as a Worst-Case Grouping Factor
October	Meaning of "Dedicated"?
September	Another Issue for API Synthesis
August	EMA's Q&A Clarification: Part 2
July	EMA's Q&A Clarification: Part 1
June	Pass/Fail Analytical Test Methods
May	Issues in Product Grouping
April	Dirty and Clean Hold Time Protocols
March	Establishing Clearance for Degraded Protein Actives
February	A Possible Approach for Biotech Limits
January	A Critique of the APIC Guideline
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?
May	More on Limits Based on Compendial Water Values
April	The 500 ppb TOC Myth
March	Using Safety Factors of Less than 0.001 of a Dose
February	Does Risk-MaPP Offer More Patient Protection?
January	Recovery Studies for Different Surfaces for Rinse Sampling

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
February	Bioburden Proliferation in CEHT Protocols
January	Acceptance Criteria for Dedicated Equipment

2005

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

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

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

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
June	Recovery Studies for Microbial Sampling?
May	Cleaning Validation for Medical Devices
April	Understanding and Applying "Visually Clean"
March	What's a Contaminant?
February	The Use of Default Limits
January	The Use of Safety Factors in Limits Calculations

2001

December	What's a "Dose" for Calculating Limits?
November	Cleaned Equipment Hold Time
October	Dirty Equipment Hold Times
September	Handling Sampling Recovery Results
August	Equipment Grouping Strategies for Cleaning Validation
July	Product Grouping Strategies for Cleaning Validation
June	Water Quality for Validated Cleaning Processes
May	Setting "Dose" Limits without Dosing Information
April	Cleaning for Manufacture of Clinical Trial Materials (CTMs)

March	The New FDA Compliance Program Guidance Manual and Cleaning Validation
February	Validation of Analytical Methods
January	Specificity of Analytical Methods

2000

November	Campaigns and Dedicated Equipment
October	The Applicability of Cleaning Validation