Top 10 in 2022

2022 has been quite the year! Unsurprisingly, new guidances and regulatory matters make a few appearances in the newsletter. Other critical issues — cleaning validation and environmental monitoring, GMPs, factory acceptance testing, and quality risk management — maintain interest while the industry continues to develop and produce critical medicines for patients in need.

As an eventful 2022 draws to a close, we encourage you to spend a few minutes reviewing the lists below — and reading (or rereading) the content you and your peers found most compelling.

Top 10 Editorials

1. FDA Updates Guidance For Investigating OOS Test Results For Pharma Production
   By Mark Durivage, Quality Systems Compliance LLC
2. SOPs, The Modern Worker, And How Pharma Companies Must Evolve The "Read And Understand" Model
   By Mark Simon and Ben Locwin
3. Replacing The MAC/MACO With The MSC: Rethinking How Cleaning Validation Limits Are Calculated
   By Andrew Walsh, Thomas Altmann, Ralph Basile, Joel Bercu, Ph.D., Alfredo Canhoto, Ph.D., Andreas Flueckiger, M.D., Igor Gorsky, Jessica Graham, Ph.D., Ester Lovsin Barle, Ph.D., Ovais Mohammad, Mariann Neverovitch, Siegfried Schmitt, Ph.D., and Osamu Shirokizawa
4. CAPA System Best Practices For GMP Compliance
   by Thomas Peither, GMP-Verlag Peither AG
5. New ICH Q14 Guidance Applies QbD To Analytical Procedures
   By Brian Glass, senior analytical consultant, Pharmatech Associates
6. Factory Acceptance Testing, Site Acceptance Testing, Commissioning Activities, Oh My!
   By Ajay Pazhayattil, Praveen Joseph, and Ciona Forsythe
7. U.S. Congress Passes Bill Supporting New Era Of Biopharma Advanced Continuous Manufacturing
   By Madeleine Giaquinto, JD, and Kalah Auchincloss, JD, MPH
8. Mold Investigations Using Biofluorescent Particle Counting Systems
   By Dawn Watson, director, Microbial Control & Sterile COE, Merck & Co., Inc.
9. How To Set Up An Effective Quality Risk Management Program
   By Peter H. Calcott, Ph.D., president and CEO, Calcott Consulting LLC
10. How AstraZeneca Optimized Vapor-Phase Hydrogen Peroxide Gassing Cycle Development With Enzyme Indicators
    By Stephen Dawson and Miriam Guest, AstraZeneca

Top 10 White Papers

1. Terminal Sterilization Of Prefilled Syringes
   By Thomas Ofenboeck and Christian Dallner, Syntegon
2. Overcome Lyophilization Challenges During Development, Scale-Up, And Manufacturing Of Biologic Products
   By Zak Yusoff, SP Industries, USA
3. Biologic Drug Products: A Five-Point Strategy For Building A CMC Dossier
   By Daniela Decina and Michele Duggan, Thermo Fisher Scientific
4. Components Of An Effective Disinfectant Prequalification Strategy
   By Mariana Breña, Christopher Parker, and Michael Mrvos, Cambrex

5. Review Of Annex 1 2022: Environmental Monitoring Changes
   By Mark Hallworth, Particle Measuring Systems
6. Why Biological Indicators Survive A Validated Cycle
   By Garrett Krushefski, Mesa Laboratories
7. What Is Pharma 4.0 And How Can You Implement It?
   By Kelly Stewart, Apprentice
8. Modernizing Biopharma Manufacturers To Improve Quality And Safety
   By David Jensen, MasterControl
9. Considerations For Prefilled Syringes For 503(b) Compounding Facilities
   By Keith Dodson, AST
10. Pharma Analysis And Quality Control: Trends From The Rapid Pharma Evolution
    By MilliporeSigma

Top 10 Case Studies

1. Selecting Sterile API Transfer Technologies
   By ChargePoint Technology
2. How Augmented Reality Increases Productivity At Bristol Myers-Squibb
   By Apprentice
3. Scale-Up And Site Transfer Of A Semi-Solid Product For Commercial Launch
   By Cambrex
4. Catalent Cell And Gene Therapy Utilizes Robotic Aseptic Filling Systems To Meet Industry Needs
   By AST
5. Aseptic T-Cell Production For Cell And Gene Therapy Manufacturing
   By Dec Group
6. Leveraging An Integrated Network To Accelerate Spray Drying And Tableting Scale-Up
   By Catalent
7. Analytical Procedure (Method) Lifecycle Management Drives Method Development At Innovative CDMO
   By Waters Corporation
8. Flexible Production: Meet The Growing Demands Of The Biotech Sector
   By Matthias Angelmaier, Syntegon Pharma Technology Inc.
9. Clinical Supply Optimization: Process Improvement Accelerates Clinical Trial Deliverables And Execution
   By Thermo Fisher Scientific
10. Simplifying Tech Transfer With Automated Data Flow
    By Dassault Systèmes Americas

Top 10 Application Notes

1. Basic Principles Of Freeze Drying
   By John Barley, SP Industries, Inc.
2. Best Practices For The Design And Manufacture Of Radiopharmaceutical Containment Hot Cells, Isolators, And Gloveboxes
   By Craig Johnson, Nuclear Containment Subject Matter Expert, at Walker Barrier System
3. Development Of An Aseptic Transfer System
   By ChargePoint Technology
4. How To Perform HPLC Method Transfer Between Analytical Testing Equipment
   By Waters Corporation
5. Pharma Manufacturing: Effect Of Insulation Coverage On Energy Savings
   By T-FIT®

6. Proper Biological Indicator Placement During Vaporized Hydrogen Peroxide Decontamination Cycles
   By Kurt McCauley, Mesa Laboratories
7. Particle Counting In Injectable Solutions
   By Particle Measuring Systems
8. Highly Potent Active Pharmaceutical Ingredients Containment
   By Scott Patterson, ILC Dover
9. Streamlining Cell Therapy Delivery With Efficiency-Led Design
   By Cytiva
10. Understanding Trace Element Variability In Custom Cell Culture Media
    By Thermo Fisher Scientific

Top 10 Solutions

1. RABS: Restricted Access Barrier System For Drug Manufacturing
   Syntegon Pharma Technology Inc.
2. Overcoming Aseptic Manufacturing Challenges To Prevent Contamination
   Dec Group
3. Vision Robot Unit: Driving Pharma Innovation
   Stevanato Group
4. Manufacturing Execution System (MES) For Cell And Gene Therapy Drug Manufacturers
   Apprentice
5. Single-Use Bioprocessing Bags
   ILC Dover
6. Double Taper Die
   Wilson Tool International
7. Palltronic Flowstar V Integrity Test Instrument
   Pall Corporation
8. Single-Use mAb Process Playbook
   Thermo Fisher Scientific
9. The Milliflex Oasis Membrane Filtration Method: Productivity And Reliability In Bioburden Testing
   MilliporeSigma
10. Drug Manufacturing Facility Management Services
    JLL

Reference

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https://www.pharmaceuticalonline.com/doc/pharmaceutical-online-top-10-of-2022-0001?utm_source=Onesignal&utm_medium=Pushnotification&utm_term=Top10