

2022 前 10 名

2022 是相當可觀的一年！不出所料，新的指南和監管事項在時事通訊中出現了一些。其他關鍵問題—清潔確效和環境監控、GMP、FAT 和 QRM—在產業繼續為(有需要的)患者開發和生產關鍵藥物時，保持關注。

多事之秋的 2022 即將結束，我們鼓勵您花幾分鐘時間查看下面的清單，並閱讀（或重讀）您和您的同行認為最引人注目的內容。

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

12.19.22 -- Pharmaceutical Online Top 10 Of 2022

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