

ADVANCE YOUR GMP DIGITAL MATURITY

Join 150+ GMP Professionals for the event of the year! Be ready to succeed in the ever-changing regulatory environment and increasing global competition by investing in advancing your organization's GMP compliance.

Wednesday, October 26: Blue Mountain RAM R4 Training & Certification Preparation

7:30 AM ET COFFEE, NETWORKING & REGISTRATION AT THE FITLER CLUB

8:30 AM ET HOW BLUE MOUNTAIN RAM SUPPORTS THE QMS

Uncover how Blue Mountain RAM supports quality systems by understanding the importance of audit readiness, reviewing how the software maps to 21 CFR Part 11, and more.

10:00 AM ET *Break*

10:30 AM ET AUDIT PREPARATION AND NAVIGATION FUNDAMENTALS IN R4

Learn the fundamentals to support audit readiness, including standardization of data, custom workspaces for audit support, and workflows and rights.

12:00 PM ET *Lunch*

1:00 PM ET AUDIT READINESS & BLUE MOUNTAIN RAM CERTIFICATION PREPARATION

Participate in scenario-based audit exercises and become prepared to earn the Blue Mountain RAM Certification and LinkedIn Badge - create helpful queries for monitoring and retrieving data and reducing risk.

3:30 PM ET *Break*

3:45 PM ET AUDIT READINESS & BLUE MOUNTAIN RAM CERTIFICATION PREPARATION CONTINUED

5:15 PM ET – 7:15 PM ET HAPPY HOUR AND NETWORKING AT THE FITLER CLUB

Drinks and hors d'oeuvres

Thursday, October 27: Customer Knowledge Share

7:30 AM ET COFFEE & NETWORKING AT THE FITLER CLUB

8:00 AM ET WELCOME TO THE 2022 BLUE MOUNTAIN SUMMIT

-- *David Rode, CEO of Blue Mountain*

8:30 AM ET CONNECTED EVERYTHING: ASSET MANAGEMENT

Explore the current state of the Life Science manufacturing and prepare your organization to take advantage of the technological momentum of being digital and agile.

-- *J.R. Hoover, Asset Lifecycle Management at Deloitte*

-- *Kirti Jindal, Life Science Consulting - Supply Chain & Network Operations at Deloitte*

9:15 AM ET UNLOCKING SUCCESS IN DIGITAL TRANSFORMATION - HOW PEOPLE AND PROCESSES ARE KEY TO INNOVATION

Becoming a future-ready organization that reaches the highest level of GMP digital maturity to maintain industry leader status and remain resilient and profitable, even under challenging circumstances.

-- *Nicholas Benetatos, Consultant: Global Regulatory Affairs, Medical Devices, and Drug Delivery at Exponent*

10:00 AM ET Break

10:15AM ET RISKY BUSINESS - COVID'S IMPACT ON RISK IN THE REGULATED INDUSTRY

Identify the highest compliance risks to your organization and learn how to make them a priority for the compliance controls, policies, and procedures. Join industry leaders to discuss how they have solved problems using risk-based approaches.

-- *Ginny Lee, Director of Professional Services at Blue Mountain*

-- *Ryan Siskey, Principal and Philadelphia Office Director at Exponent*

-- *Jacqueline Berman, FDA Partner at Morgan, Lewis & Bockius LLP*

-- *Dr. Ram Arthanari, Senior Delivery Manager at Verista*

11:15 AM ET DATA ARCHITECTURE BEST PRACTICES FOR PHARMA 4.0™

Explore how HighByte's Industrial DataOps solution address the data architecture and integration needs of life science companies as they adopt Industry 4.0, Digital Transformation, and Smart Manufacturing.

-- *John Harrington, Co-Founder and Chief Product Officer at HighByte*

-- *Bill Lucas, Chief Platform Architect at Blue Mountain*

12:00 PM ET Lunch

1:00 PM ET DELIVERING SAFE & EFFECTIVE DRUGS: SCALING WITH EXTERNAL RESOURCES

Learn about the challenge of creating a scalable, compliant manufacturing process for vein-to-vein therapies in a fast-paced startup. This presentation will cover the role of managed service providers in accelerating quality and manufacturing initiatives given limited resources and challenges in hiring and training.

- David Rode, CEO of Blue Mountain
- Dr. Ram Arthanari, Senior Delivery Manager at Verista
- Aaron Hubbel, VP of Business Development at Verista
- Nick Lukkarila, Quality IT Systems Analyst III at Amplify-Bio
- Ginny Lee, Director of Professional Services at Blue Mountain

1:45 PM ET BUILDING A CULTURE OF COMPLIANCE

Join industry experts for a discussion around identifying gaps in compliance programs and opportunities to improve compliance culture, including the adoption of innovative technologies.

- Chris Corsetti, Director of Facilities at ElevateBio
- Matt Nolin, Owner, Nolin Control Systems
- Beth Lafreniere, Director, Laboratory Support Services at KCAS
- Yijia Sun, Quality Assurance Manager at Blue Mountain

2:30 PM ET EVOLVING BLUE MOUNTAIN RAM IN SUPPORT OF DIGITAL TRANSFORMATION

Join veteran users to discuss how they have evolved their uses of Blue Mountain RAM in respect to the lasting impacts COVID-19 has had on existing processes and an organizations' Industry 4.0 ambitions.

- Crystal Martinez, CMMS Program Manager at Cepheid
- Donald Stuck, Director, Global Facilities Operations at 2SeventyBio
- Beth Burgess, Facilities Coordinator IV at Regeneron Pharmaceuticals
- Colin DeMoss, Implementation Services Lead at Blue Mountain

3:15 PM ET Break

3:30 PM ET GLOBAL PROCESS IMPROVEMENT AND ENTERPRISE MANAGEMENT

Join speakers from global Life Science companies for a discussion around how driving continuous improvement in people, processes, and software lead to increasingly compliant and productive electronic systems.



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- *David Porrill, SME for Reliability Standards, Processes and Systems at Catalent*
- *Erik Hobizal, Calibration Manager, Quality Operations Engineering at Cepheid*
- *Chris Tencza, Site Director at Vertellus*
- *Jonathan Pingley, Implementation Manager at Blue Mountain*

4:15 PM ET [BLUE MOUNTAIN PRODUCT ROADMAP](#)

See where Blue Mountain is headed in 2023 and 2024 – gaining a sneak peek at upcoming product and feature releases.

- *Jonathan White, Chief Technology Officer at Blue Mountain*

4:45 PM ET [CLOSING REMARKS](#)

6:30 PM ET – 8:30 PM ET [HAPPY HOUR AND NETWORKING EVENT AT THE FRANKLIN INSTITUTE](#)

Drinks and hors d'oeuvres

Friday, October 28: Blue Mountain 2022 and Beyond

7:30 AM ET COFFEE & NETWORKING AT FITLER CLUB

8:00 AM ET UPGRADING TO BLUE MOUNTAIN RAM R4 Q&A

Hear from fellow customers on the factors that influenced their organizations to upgrade from R3 to R4, their path to rolling out R4, and how they measure success.

-- *Brendan Walles, Analyst II, Engineering & Manufacturing Systems at Oxford Biomedica Solutions*

-- *Nick Sturniolo, Implementation Services Lead at Blue Mountain*

8:30 AM ET BLUE MOUNTAIN RAM R4 OVERVIEW AND Q&A

Join us for a demo of the latest release of Blue Mountain RAM to see R4 live and partake in a Q&A session with our team.

-- *Adam Abbott, Solutions Engineer at Blue Mountain*

9:15 AM ET INTRODUCING GMP INSIGHTS

Get an exclusive look at the new Power BI dashboards directly in Blue Mountain RAM for interactive visualization of data. Empower your organization to discover insights to improve manufacturing.

-- *Nathaniel Matthews, Product Manager – Templates Delivery Operations at Blue Mountain*

-- *Angelo Kwak, Report Developer II at Blue Mountain*

-- *Adam Abbott, Solutions Engineer at Blue Mountain*

9:45 AM ET WHAT'S NEW IN THE BEST PRACTICES TEMPLATE

Discover how new software features can help your organization streamline operations across departments.

-- *Nick Sturniolo, Implementation Services Lead at Blue Mountain*

-- *Nathaniel Matthews, Product Manager – Templates Delivery Operations at Blue Mountain*

-- *Jonathan Pingley, Implementation Manager at Blue Mountain*

10:15 AM ET Break

10:30 AM ET DIGITAL RESOURCE PLANNING AND SCHEDULING & R4 INTEGRATION

Learn about the integration capabilities of Blue Mountain RAM R4 in the Cloud and explore an integration use case with SmartQC by cResults.

-- *Rafi Maslaton, President at cResults*

-- *Keith Kyle, Director of Sales at Blue Mountain*



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11:00 AM ET INTRODUCING CENTER OF EXCELLENCE AND PEAK CONSULTING SERVICES

Get a preview into our new services, including Blue Mountain's Center of Excellence (new and improved R3 and R4 eLearning courses, webinars, training, and more) and PEAK Consulting Services.

-- *Lucas Vilca, Strategic Account Manager at Blue Mountain*

-- *Scott Fry, Director of Customer Operations at Blue Mountain*

11:30 AM ET CLOSING REMARKS