

REPHINE SYMPOSIUM 2023

Live online event
April 17th - 18th, 2023

Introduction

Rephine Virtual Symposium is an annual event which was delivered online previously with great success in 2021. The Symposium is a great opportunity to deliver our deep domain expertise within the Quality Assurance scope.

Objectives

Knowledge Transfer

Delivering our thought leadership expertise to our intended audience

Awareness of Rephine's capabilities and in house expertise

Highlight best practices and guidelines for updated industry regulations

Intended audience

This event is addressed to all professionals that are involved in the Supply Chain of raw materials for the pharmaceutical industry. Especially for those professionals in:

- Qualified Persons and Quality Directors
- Purchasing or Quality departments of Pharmaceutical companies
- Chemical Distribution companies
- EU GMP inspectorates
- API and Excipients manufacturers

Programme

PART 1. April 17th, 2023. 9:00 am - 12:30 pm GMT

SESSION 1

09:00 - 09:15h Welcome to the Symposium.
Adam Sherlock. Rephine CEO.

09:15 - 09:30h Why this Symposium?
Chris Burman. Rephine VP Commercial

09:30 - 10:30h Evolving with Good Manufacturing Practice: harnessing the new risk-based approach to improve proactivity & process efficiency.
Dr. Eduard Cayón. Rephine VP Audit Services.

10:30 - 10:45 h Coffee Break

SESSION 2

10:45 - 11:00 h Auditing Best Practices – Gold Standard approach (I)

- *Absence of conflict of Interest*
- *Confidentiality and Full transparency*

Alasdair Leckie. Rephine VP GMP Operations

11:00 - 11:30 h Auditing Best Practices – Gold Standard approach (II)

- *Audit preparation, risk based*
- *Auditor expertise and knowledge*
- *Reporting focussed to QP needs*

José Carlos Vergara & Tábata Bortuni. Rephine Heads of technical department

11:30 - 11:45 h Auditing Best Practices – Gold Standard approach (III)

- *Quality Oversight of auditing process*

Aina Sellés. Rephine Quality Director

SESSION 3

11:45 - 12:30 h GMP 2023 Trends Roundtable
(Anna Cluet, Eduard Cayon, Vera Wang)

Closing remarks: Adam Sherlock

PART 2. April 18th, 2023. 9:00 am to 12:30 pm GMT

SESSION 4

09:00 - 10:00h Digitalisation of manufacturing quality management: optimising the potential by redesigning processes.
Marian San. Rephine VP Consulting.

Sandra Lacruz. Pharmaceutical Senior Consultant

10:00 - 10:15 h Coffee Break

SESSION 5

10:15 - 11:00h **GMP & Quality data integrity: how to approach & demonstrate this.**
Sergi Arcas. Rephine Senior Consultant CSV

SESSION 6

11:00: - 11:30 h **Importance of eQMS in the pharmaceutical industry (Trackwise Case Study).**
Victor Samitier. Rephine Trackwise Delivery Manager. Trackwise area manager
Roberto Palomar: Rephine Trackwise Delivery Consultant

SESSION 7

11:30 - 12:00 h **Digital transformation of paper-based validation methodologies (Valgenesis Case Study).**
Juan Torrijos. Rephine Validation & GMP Consultant. Valgenesis area manager

SESSION 8

12:00 - 12:30 h **News on European Regulatory framework for Medical Devices**
Laia Paris. Rephine Medical Device consultant.

Closing remarks: Adam Sherlock