



September 10th
to
October 10th, 2024

13:00 to 15:30 CEST
Twice a week

2024 Virtual cGMP Training Marathon for Vaccine Manufacturing:

Institutionalizing Compliance and Continued Improvement

The WHO Local Production and Assistance Unit (LPA), with financial support from the Bill & Melinda Gates Foundation (BMGF), is organising the fifth Virtual cGMP Training Marathon for Vaccine Manufacturing. This event, titled “Institutionalizing Compliance & Continued Improvement,” aims to strengthen the capacities of vaccine manufacturers, particularly in low- and middle-income countries, ensuring sustainable access to quality-assured vaccines. This year’s training will build on the success of previous years, focusing on new technologies, regulatory updates, and best practices to help participants maintain ongoing cGMP compliance and foster a mature quality culture in their manufacturing processes. The marathon will be conducted virtually from September 10 to October 10, 2024, and will feature interactive sessions designed to equip and enhance participants’ knowledge, skills, and compliance with international guidance and regulatory requirements in vaccine manufacturing.

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2024 Virtual cGMP Training Marathon for Vaccine Manufacturing

Institutionalizing
Compliance and
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Intended Participants

Professionals engaged in vaccine, biological, and pharmaceutical manufacturing, including those involved in development, quality control, quality assurance, and regulatory affairs, will benefit the most from the Fifth Virtual cGMP Training Marathon. This event is particularly aimed at technical staff from vaccine and biopharmaceutical manufacturers, regulators, and government representatives, with priority given to participants from low- and middle-income countries. Prior knowledge of current WHO GMP standards is required. Registration is necessary, and priority will be given to participants from LMICs and manufacturers with active plans for WHO prequalification/EUL.

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Topic Highlights

- 10/09** Bio-analytical method development and validation ICH Q2(R2) and ICH Q14 for biologicals – Implementation and inspection-related considerations.
- 12/09** Quality risk management framework – a proactive, data-driven and integrated approach.
- 17/09** Process validation of biologicals – meeting current regulatory expectations.
- 19/09** Roadmap to maintaining and improving process performance via monitoring and trending.
- 24/09** Sterile manufacturing TRS 1044 Annex 2 - navigating complexities and practical solutions.
- 26/09** Technology transfer granularities – understanding essentials and key activities for biopharmaceuticals.
- 01/10** Management of GXP outsourced activities - challenges and strategies to safeguarding your process.
- 03/10** Maintaining compliant critical utilities from URS to PQ.
- 08/10** CAPA and RCA investigation management - improving effectiveness.
- 10/10** Recent cGMP inspection trends – common non-compliances and typical pitfalls.

Registration of interest to participate is required. All registrations of interest will be reviewed, and only selected registrants will receive a link for participation. The deadline for registration is September 6th, 2024.



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