

## **Deviation Manager- Bioconjugates**

## **Job Description Summary**

Today Lonza is a global leader in life sciences operating across three continents. While we work in science, there's no magic formula to how we do it. Our greatest scientific solution is talented people working together, devising ideas that help businesses to help people. In exchange, we let our people own their careers. Their ideas, big and small, genuinely improve the world. And that's the kind of work we want to be part of.

The Deviation Manager (m/f/d) will be part of a team that is currently established to own and investigate deviations at our Bioconjugates facilities in MC1 and PCP.

He/She represents the Operations Unit, taking ownership of Deviations which arise; to investigate the root cause(s), the impact/potential impact on product and/or systems, and to define appropriate CAPA(s) as solutions.

## Key Responsibilities:

- Responsible to own, investigate, author, and record assigned Deviations.
- Liaise with Subject Matter Experts (SMEs) and key stakeholders to establish the root cause(s) of deviations and the potential impact of said deviations.
- Ensure proper investigation tools are used to systematically define all root causes and contributing factors (e.g. Logic Fault Tree, Defense analysis, Event & Causal Factors chart, Fishbone).
- Define and agree with SMEs appropriate CAPA(s), and associated Effectiveness Checks.
- Ensure cGMP compliance and consistency through the investigation process and drive their quality records to completion and closure according to scheduled release times.
- · Support the business through ongoing change and process improvement activities.

## Key Requirements:

- · Bachelor degree in chemistry, biotechnology, life science or related field.
- Previous experience in Deviations and cGMP in a regulated pharmaceutical/API industry is a strong advantage.
- Knowledge of biotech or bioconjugation manufacturing processes and analytical methods is an advantage.
- Experience with Human and Organizational Performance & risk management approaches is an advantage.
- Fluency in English, written and spoken. German is an advantage.
- Technical writing & presentation/communication skills are key for the role. Demonstrated previous experience is a strong advantage.
- Structured, focused and well-organized working attitude; open-minded for new ideas and suggestions; agile, highly motivated and dynamic drive.
- Ability to work with and lead a team of SMEs without formal authority as well as to deliver full
  projects working independently.

Lonza's products and services have a positive impact on millions of people. For us, this is not only a great privilege, but also a great responsibility. How we achieve our business results is just as important as the achievements themselves. At Lonza, we respect and protect our people and our environment. Any success we achieve is no success at all if not achieved ethically.

People come to Lonza for the challenge and creativity of solving complex problems and developing new ideas in life sciences. In return, we offer the satisfaction that comes with improving lives all around the world. The satisfaction that comes with making a meaningful difference.