



Let's talk ATMP – A workshop on GMP for ATMP and their regulatory requirements

Topics:

- #Late state development transitioning to GMP
- #Requirements to starting materials for ATMP
- #Supplier and ATMP manufacturer relationship

21. May 2026, 10 AM – 14:30 PM

With Speaker and Moderators:

Dr. Robert Zoubek, Granzer Regulatory Consulting & Services GmbH
Dr. Hans-Georg Eckert, Valicare GmbH
Dr. Stefan Löffler, Valicare GmbH

Veranstaltungsort: Rahel Hirsch Centre for Translational Medicine
Luisenstraße 65, 10117 Berlin

Agenda

- 10:00 -10:15** Welcome & Blitz-Introduction of Participants
- 10:15 - 10:45** Session 1: Individualized Therapies — Current regulatory perspective; 20 min Presentation & 10 min QA
- 10:45 - 11:15** Session 2: GMP regulatory framework with current news and outlook; 20 min Presentation & 10 min QA
- 11:15 – 12:30** Impuls lecture on requirements to starting and ancillary materials for ATMPs (10min) followed by a hands-on session: QTTP to Specification of a starting material
- 12:30 - 13:00** Lunch break
- 13:00 – 13:30** Session 3: Supplier qualification management and supplier qualification audit in GMP; 20 min Presentation & 10 min QA
- 13:30 – 14:15** Open format exchange on: Selecting, qualifying and handling a contract manufacturing organization 45 min
- 14:15 – 14:30** Closing, takeaways & feedback

Die Teilnahme ist kostenlos, aber es besteht Anmeldepflicht!
Teilnahmeanfragen bitte an: stefan.loeffler@valicare.com.