ONLINE TRAINING

Radiopharmaceuticals: A practical CMC and quality perspective

Navigating current & future EMA requirements/ EU regulatory standards

TOPICS

- The new EMA quality guideline: Structure and core requirements
- CDMO (Contract Development and Manufacturing Organisation) contribution to CMC strategy and regulatory dossier integration
- The sponsors perspective: Owning CMC strategy across the lifecycle

YOUR SPEAKERS

Fernando Blanco Rodríguez
Agencia Española de Medicamentos y Productos Sanitarios (AEMPS),
Madrid, SPAIN

Steffi Wittmann
ITM Isotope Technologies Munich SE,
Garching, GERMANY

Dr Natalia Ladygina
Trasis SA,
Ans, BELGIUM

12 NOVEMBER 2026 - ONLINE

Aims and objectives

Radiopharmaceuticals are subject to a rapidly evolving regulatory landscape. At its centre stands the ongoing revision of the EMA's core quality guideline. Beyond this revision, further legislative updates are on the horizon (e.g. revision of ICH M4Q, emerging EU additional quality master file system).

This seminar provides a practical, application-oriented overview of the current and forthcoming EU regulatory framework for radiopharmaceuticals, covering CMC and quality requirements. Bringing together regulatory authority, CDMO, and sponsor perspectives in one program, participants gain both a solid understanding of regulatory requirements and direct insight into how they translate into daily practice, also at the "interfaces".
With regulatory revisions still in progress, early awareness is key, giving your company the opportunity to assess implications and start preparing in good time.

Please note that the content addressed on the EMA Guideline on Quality of Radiopharmaceuticals refers to the draft version of the guideline currently in place.

Who should attend?

This seminar is designed for regulatory affairs specialists and CMC managers working with radiopharmaceuticals in pharmaceutical companies, hospital pharmacies, CDMOs, or regulatory authorities who need to navigate the current and upcoming EMA requirements with confidence.

YOUR SPEAKERS

Fernando Blanco Rodríguez

Agencia Espanola de Medicamentos y Productos Sanitarios (AEMPS), Madrid, SPAIN
Chemical and Pharmaceutical Division

Fernando Blanco is a healthcare and regulatory professional with a degree in Chemistry and expertise in Clinical Analysis and Radiopharmacy. With over two decades of experience in quality assurance, he currently serves as a Quality Assessor at the Spanish Agency of Medicines and Medical Devices (AEMPS) and contributes to the European Pharmacopoeia as an expert in radiopharmaceutical preparations.

Dr Natalia Ladygina

Trasis SA, Ans, BELGIUM
Regulatory Affairs CMC Expert
Radiopharmaceuticals

Natalia holds a background in biology with 10 years of research experience. She subsequently transitioned into regulatory affairs and has been working in the radiopharmaceutical industry for more than eight years.

Steffi Wittmann

ITM Isotope Technologies Munich SE, Garching, GERMANY

Senior Regulatory Affairs CMC Manager

Steffi Wittmann is a pharmacist with over ten years of experience in the pharmaceutical industry, currently serving as Senior Regulatory Affairs CMC Manager at ITM Isotope Technologies Munich SE. She holds a degree in Pharmacy from the University of Leipzig.

Your program from 9:00 am until 5:00 pm CET

Welcome, introduction, expectations

The new EMA quality guideline: Structure and core requirements

Fernando Blanco Rodríguez

- The legal and regulatory EU framework:
  - Key changes
  - Scientific Guidelines and
  - Texts of the Ph.Eur.
- Background and objectives of the revision: What changes compared to Revision 1 (2008)? Integration into the CTD framework (module 3)
- Active substance: Content of module 3.2.S for
  - Radionuclide precursor
  - Active substance and chemical precursor
  - Radiolabelled active substance
- Finished product: Content of module 3.2.P for drug products for different purpose

CDMO contribution to CMC strategy and regulatory dossier integration

Dr Natalia Ladygina

- CMC data integration: ASMF, CEP, and unreferenced master file pathways
- Comparison of the regulatory pathways, incl. their suitability across development stages (e.g. clinical vs. MAA)
- Clarification of sponsor vs. CDMO responsibilities
- Integration of CDMO data into module 3
- Management of critical quality risks
- Practical recommendations to build robust/ consistent regulatory dossiers

The sponsors perspective: Owning CMC strategy across the lifecycle

Steffi Wittmann

- Strategic CMC planning across development stages:
  - Phase-appropriate data packages and regulatory expectations
  - From IMP to marketing authorisation
- CDMO oversight from a regulatory perspective
- Variation management and lifecycle planning: Typical CMC changes, regulatory impact, submission strategy
- Navigating regulatory uncertainty as a sponsor:
  - Interpreting guidelines, managing regional differences and aligning cross-functional input
  - Proactive health authority interaction and adapting to evolving regulatory expectations
- Lessons learned:
  Common pitfalls in CMC strategy, and how to prevent them

Recap and outstanding questions

Radiopharmaceuticals: A practical CMC and quality perspective

REGISTRATION UNDER

service@forum-institut.com
www.forum-institut.com
Webcode 26112455

Tel. +49 6221 500-500
Fax +49 6221 500-555

REGISTRATION FORM

Yes, I will attend

☐ Radiopharmaceuticals: A practical CMC and quality perspective

☐ Yes, I agree that FORUM Institut may inform me about events by: ☐ email; and/or ☐ telephone. I may withdraw my consent at any time.

Name

Position, department

Company

Street

Post code, city, country

Tel. no./Fax no.

E-mail

Contact person at office

Date, signature

Date
Thursday, 12 November 2026 - Online training
from 9:00 am until 5:00 pm CET
You may dial in 30 minutes before the lecture starts

Fee
€ 1290.00 (+ German VAT)
The fee includes high-quality course material and a participation certificate for download, access to the Learning Space as well as technical support.

How our online events work

- Our online events are live and interactive. They can be accessed in the Learning Space, where you will also find the programme, the list of participants and all relevant documents.
- You can access the Learning Space with the same account you use for the customer portal.
- The free pre-meeting helps you resolve any technical issues before the event.
- Continuous support during the online event guarantees that you concentrate entirely on the training.
- We guarantee the highest quality according to ISO 9001 and ISO 21001.

CANCELLATION POLICY

Our general terms and conditions (as of 01 June 2024) apply and are available upon request. We can send them to you at any time. Alternatively, you can access them online at www.forum-institut.com/t&c

YOUR CONTACT

Dr Birgit Wessels
Conference Manager
Tel. +49 6221 500-652
b.wessels@forum-institut.de