pharmakon

CMO Management and Technology Transfer in GxP

Solve key external partners challenges with more control

Do you work with external partnership and need stronger control and a structured technology transfer to secure quality, compliance and patient safety? This course gives you a practical framework for managing external partners.

Working and collaborating with external partners such as CMOs, CDMOs, and CROs is a core element of many life science strategies and often brings practical challenges. You may need to clarify responsibilities, strengthen the quality agreements, improve communication, prepare audits, manage batch release or plan safe transfer of product and process knowledge to another site.

This course gives you a practical framework to handle these tasks of managing external partners and performing technology transfer in regulated environments in a structured and compliant way:

- You learn how to assess partner maturity, select the right CMO/CDMO/CRO, manage cultural and language barriers, and understand regulatory expectations for outsourced activities
- You learn how responsibilities are shared between sponsor and partner, how to plan and conduct audits, and how regulatory obligations such as batch release and QP responsibility are handled
- You also gain a structured approach to technology transfer from preparation to routine production.

The course takes you through the purpose, requirements, governance and phases of technology transfer so you can plan and manage a transfer from preparation to routine operation.

You work with risk, documentation, training, process and analytical transfer, verification and formal handover between sending and receiving sites.

This course alternates between short lectures, case work, and group exercises. This helps you turn theory into practical action and apply the principles directly in your daily work.

On the course you will meet:

Pourya Vali, Principal Consultant & Founder, Nordic GxP Compliance

Thomas Sølver, Expertise Director, NIRAS

Course facts

FORMAT
2 days

PRICE THIS YEAR
17.500 DKK excl. VAT, overnight stay included

Sign-up dates

Hillerød

3. nov. — **4. nov.**
2026

Do you have questions about this course?

Kontakt
Kursuskoordinator
Andreas Goldschadt
+45 48 20 62 63
ag@pharmakon.dk

Target group

The course is relevant for professionals in QA, RA, QC, manufacturing, supply chain, and project functions who work with external manufacturers or transfer projects. It is especially useful for those who are new to the area or who want a stronger and more structured foundation.

Your benefits

- you can assess and select partners based on maturity, competence and risk
- you can prepare and follow up on quality agreements and create clarity on roles & responsibilities, handling audits, batch release activities and QP obligations
- you can plan and manage a technology transfer in phases with clear tasks and deliverables, manage knowledge transfer and identify and mitigate risks

Your company's benefits

- your employees can strengthen the company's control of CMO, CDMO, and CRO partnerships and reduce risk in outsourced activities
- your employee can support stronger quality agreements, clearer responsibilities, and better collaboration across QA, QC, QP, RA, and manufacturing
- your employee can run technology transfer in a more structured way, helping the company improve quality, compliance, and supply security

Course agenda

The course duration is 2 days. Accommodation is included.

Collaboration with CMO, CDMO and CRO's – why it requires more than a contract incl.:

- Regulatory requirements and authority expectations for outsourced activities
- Assessment of CMO/CDMO/CRO: maturity, competence, and compliance
- Quality agreements: structure, negotiation, follow-up, and interfaces
- Risk assessment of external partners and outsourced activities
- Roles and responsibilities: sponsor vs partner (including QP and batch release)
- Release activities (QP, QA, QC)
- Culture and communication: managing language and cultural barriers

Technology Transfer; purpose, operation, regulatory framework and overview incl.:

- Audit program: planning, execution, and follow-up
- Regulatory requirements and authority expectations for technology transfer
- Why a technology transfer is performed (capacity, cost, lifecycle, compliance)
- When a technology transfer is required (new site, new CMO, major process changes)
- Responsibilities and governance between sending and receiving site
- Project organisation and role allocation across QA, QC, QP, Manufacturing, and RA
- Documentation and knowledge transfer o Criteria for completion of a technology transfer

Sign up online at
www.pharmakon.dk