

**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 Sølvér, 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  
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## Target group

This course is aimed at beginners and professionals with no previous hands-on experience in CMO/CDMO/CRO management and technology transfer.

It is intended for individuals who need an understanding of outsourcing and technology transfer processes, terminology, regulatory expectations, governance, roles and responsibilities, but who are not yet experienced practitioners within these disciplines.

The course provides a structured introduction and practical foundation for professionals entering the field or taking on responsibilities related to external partner management and technology transfer.

Participants with extensive practical experience in managing external partners or leading technology transfer projects should be aware that the course is designed as an introductory and foundation-level course.

## 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](http://www.pharmakon.dk)