ngee ann cet academy

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COMMISSIONING, QUALIFICATION & VALIDATION (CQV) IN THE PHARMACEUTICAL INDUSTRY

Course Duration: 70 hours | Mode: Blended Learning

Boost Your Career in Biotech and Pharma

Singapore's pharmaceutical and biotech sectors are expanding rapidly — and so should your career. Designed for professionals and recent graduates, NP's **School of Life Sciences and Chemical Technology**'s "**Commissioning, Qualification & Validation (CQV) in the Pharmaceutical Industry**" short course equips you with the critical knowledge and practical skills needed to succeed in GMP-regulated environments.

Why Join This Programme?

- ☑ Blended Format: Flexible **online lectures** + **in person instructor-led training** with industry experts
- ☑ Career-Focussed Skills: Develop Validation Master Plans, implement paperless CQV using Kneat and meet **global regulatory standards (FDA, EMA, ICH)**
- ☑ Recognised Certification: Receive a **Certificate of Completion from Ngee Ann Polytechnic** and a Kneat End User Certificate from Nd – a KneatGx™ Services Partner

What You Will Learn

- **Quality Risk Management** and Pharmaceutical Quality Systems
- **Process Validation Lifecycle** and Quality by Design
- **CQV regulatory expectations** and documentation
- Execution of Cleaning and **Paperless Validation using Kneat**

Who Should Attend?

- **CQV Engineers** and Project Engineers in Pharma
- **Life science graduates** with 1–2 years' experience

Skillsfuture Credit (SFC) eligible. Terms and conditions apply.

for.edu.sg

https://for.edu.sg/lsct-cqv-edm

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Class Schedule

Sessions	Topics & Dates	Date and Time
1	**ICH Q8** This topic explores **ICH Q8** and **Quality by Design (QbD)** principles, focusing on linking process parameters to product quality. It covers **design space definition**, process controls, and material attributes (APIs, excipients, packaging). Case studies demonstrate QbD applications, while regulatory insights guide implementation in drug development and manufacturing for consistent quality.	**Online learning:** 30/3/26 – 6/4/26 **Practicum:** 6 Apr 2026 (Mon) 6.30-9.30 pm Ngee Ann Poly
2	**ICH Q9** This topic covers **ICH Q9's** principles of **Quality Risk Management (QRM)** in pharma. Participants learn risk assessment methodologies, key tools (FMEA, HACCP, etc.), and practical integration into industry and regulatory practices. Through case studies and discussions, attendees gain skills to systematically identify, analyze, and mitigate risks to ensure product quality and compliance.	**Online learning:** 26/3/26 – 9/4/26 **Practicum:** 9 Apr 2026 (Thu) 6.30-9.30 pm Ngee Ann Poly
3	**ICH Q10** This topic covers **ICH Q10 guidelines** on **Pharmaceutical Quality Systems (PQS),** including quality policy, planning, risk management, and continuous improvement. It explores regulatory expectations, change management, and outsourcing controls. Through case studies and discussions, participants learn to implement and maintain an effective PQS for compliance and product quality in the pharmaceutical industry.	**Online learning:** 30/3/26 – 13/4/26 **Practicum:** 13 Apr 2026 (Mon) 6.30-9.30 pm Ngee Ann Poly

4&5	**Equipment and Facility Design (I) & (II)** This topic explores **Facility design principles, equipment design principles, clean utilities,** and **emerging trends and technologies** in E&F design.	**Online learning:** 2/4/26 – 20/4/26 **Practicum:** 16 Apr 2026 (Thu) and 20 Apr 2026 (Mon) 6.30-9.30 pm Ngee Ann Poly
6	**Commissioning & Qualification (I)** This topic covers **Commissioning & Qualification** principles, including **FAT/SAT, DQ/IQ/OQ/PQ**, and process validation stages. Learn to identify **CPPs, CQAs, CDEs**, and apply **risk-based methodologies** per ISPE guidelines. Hands-on case studies explore system acceptance, testing, and QRM to ensure compliance and operational readiness in regulated environments.	**Online learning:** 9/4/26 – 23/4/26 **Practicum:** 23 Apr 2026 (Thu) 6.30 pm -9.30 pm Ngee Ann Poly
7&8	**Kneat End User Training & Certification** This hands-on course trains users on **Kneat's e-Validation software**, covering document/folder creation, editing, review, and approval. Learn to manage **test execution, deviations, smart tables, and reports** using templates and cross-referencing. Gain proficiency in **data import/modification** and streamline validation workflows for compliance and efficiency in regulated environments.	**Online learning:** 18/4/26 – 9/5/26 **Online synchronous session:** 2 May 2026 (Sat) and 9 May 2026 (Sat) 10 am – 5:00 pm
9	**Commissioning & Qualification (II)** This topic covers **Commissioning & Qualification** principles, including **FAT/SAT, DQ/IQ/OQ/PQ**, and process validation stages. Learn to identify **CPPs, CQAs, CDEs**, and apply **risk-based methodologies** per ISPE guidelines. Hands-on case studies explore system acceptance, testing, and QRM to ensure compliance and operational readiness in regulated environments.	**Online learning:** 27/4/26 – 11/5/26 **Practicum:** 11 May 2026 (Mon) 6.30 pm -9.30 pm Ngee Ann Poly

10	**Process Validation** This topic covers the **Process Validation Lifecycle—Process Design, Qualification (CQV/PV), and Continued Process Verification (CPV)**. Learn **prospective, concurrent, and retrospective validation** approaches, **Validation Master Plan** development, and protocol/reporting requirements. Focuses on **risk-based strategies** and **CPV** to ensure sustained product quality and regulatory compliance.	**Online learning:** 30/4/26 – 14/5/26 **Practicum:** 14 May 2026 (Thu) 6.30-9.30 pm Ngee Ann Poly
11	**Cleaning Validation** This topic covers **cleaning validation principles**, including **SOP development, protocol design, and sampling methods**. Learn **CIP cycles, worst-case scenario selection**, and compliance with regulatory guidelines. Case studies provide practical insights into effective cleaning validation strategies to ensure contamination control and meet industry standards.	**Online learning:** 4/5/26 – 18/5/26 **Practicum:** 18 May 2026 (Mon) 6.30-9.30 pm Ngee Ann Poly

** **Online learning materials** will be provided two week prior to the Practicum sessions, enabling participants to study at their own pace. The **Practicum** will be held **in-person** at Ngee Ann Polytechnic and will feature case studies, hands-on activities, presentations, discussions, and more, providing learners with opportunities to apply their knowledge.*

For Inquiries, please contact:
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