ngee ann cet academy

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

Class Schedule

Weeks	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:** 25/7/25 – 31/7/25 **Practicum:** 31/7/25 (Thu) 6.30-9.30 pm
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:** 1/8/25 – 7/8/25 **Practicum:** 7/8/25 (Thu) 6.30-9.30 pm
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:** 8/8/25 – 14/8/25 **Practicum:** 14/8/25 (Thu) 6.30-9.30 pm

4 & 5	**Commissioning & Qualification** 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:** 15/8/25 – 28/8/25 **Practicum:** 21/8/25 (Thu) and 28/8/25 (Thu) 6.30-9.30 pm
6 & 7	**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:** 29/8/25 – 13/9/25 **Practicum:** 6/9/25 (Sat) and 13/9/25 (Sat) 9.30 am - 5.30 pm
8 & 9	**Equipment and Facility Design** This topic explores **Facility design principles, equipment design principles, clean utilities,** and **emerging trends and technologies** in E&F design.	**Online learning:** 12/9/25 – 25/9/25 **Practicum:** 18/9/25 (Thu) and 25/9/25 (Thu) 9.30 am - 5.00 pm
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:** 26/9/25 – 02/10/25 **Practicum:** 2/10/25 (Thu) 6.30-9.30 pm

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:** 3/10/25 – 9/10/25 **Practicum:** 9/10/25 (Thu) 6.30-9.30 pm

** **Online learning materials** will be released one week prior to the Practicum sessions, allowing participants to study them at their own pace. The **Practicum** will take place **in person** at Ngee Ann Polytechnic, utilizing case studies, hands-on activities, presentations, discussions, etc.*

REGISTRATION:
https://www.cet.np.edu.sg/stms_course/commissioning-qualification-validation-cqv-in-the-pharmaceutical-industry-classroom-asynchronous-e-learning/

*This course is also **SkillsFuture credit eligible**. Singaporeans and PR can enjoy up to **90% subsidies** on course fees!*

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

Want to learn more? Please contact:
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