List of approved Continuing Professional Development Activities (for Pharmaceutical Manufacturers)

The following tables list out the Continuing Professional Development ("CPD") activities approved by the Pharmacy and Poisons (Manufacturers Licensing) Committee for Authorized Persons ("APs") and other key personnel of pharmaceutical manufacturers including pharmaceutical manufacturers for advanced therapy products.

Please refer to the "Guidance on Qualification, Experience and Training Requirements for Authorized Persons and Other Key Personnel of Licensed Manufacturers in Hong Kong" for details of the CPD requirements and the classification of Category 1 and Category 2 Activities.

Please be reminded that topics of the training enrolled by the Authorized Persons and other key personnel should be relevant to their role and duties with respect to the types of manufacturing operations undertaken by the pharmaceutical manufacturers for whom they work.

CPD training topics that are relevant to the role and duties of an AP for Pharmaceutical Manufacturers include but are not limited to:

a. Role and professional duties of an AP
b. Quality management systems
c. Quality risk management
d. Qualification & validation
e. PIC/S GMP Guide and Annexes
f. Pharmaceutical manufacturing or technology
g. Pharmaceutical packaging
h. Warehousing
i. Pharmaceutical microbiology
j. Sampling, analysis and testing of pharmaceuticals
k. Active pharmaceutical ingredients
l. Mathematics and statistics related to pharmaceuticals
m. Registration of pharmaceutical products.

CPD training topics relevant to the role and duties of Head of Production or Quality Control include, but are not limited to:

a. Quality management systems
b. Quality risk management
c. Qualification & validation
d. PIC/S GMP Guide and Annexes
e. Pharmaceutical manufacturing or technology
f. Pharmaceutical packaging
g. Warehousing
h. Pharmaceutical microbiology
i. Sampling, analysis and testing of pharmaceuticals.

I. Category 1 Activities organized by LOCAL training providers-

Name of Training Provider		(1) The Hong Kong Institute of Biotechnology Limited	
Course Code	**Category**	**Title of CPD Training Programme**	**CPD Hour(s)**
CPD/L/01/2017	1A	Current Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP Guide	7
CPD/L/02/2017	1A	Pharmaceutical Quality Management Systems (PQS)	14 or 7 (when held online)
CPD/L/03/2017	1A	Risk Management in Pharmaceutical Manufacturing	14
CPD/L/04/2017	1A	Quality Risk Management Workshop	7
CPD/L/05/2017	1A	Product Quality Review (PQR) Workshop	7
CPD/L/06/2017	1A	Analytical and Microbiological Method Validation	14
CPD/L/07/2017	1A	Cleaning Validation	14
CPD/L/08/2017	1A	Process Validation	14
CPD/L/09/2017	1A	Pharmaceutical Statistics and Process Understanding applicable to PIC/S cGMPs	14
CPD/L/10/2017	1A	A Practical Approach to Pharmaceutical Commissioning and Qualification	14
CPD/L/11/2017	1A	Pharmaceutical Water System – from Design, Qualification to Control	14
CPD/L/12/2017	1A	Validation of Critical Services and HVAC	14
CPD/L/13/2017	1A	PIC/S Compliant Environmental Monitoring Program	14 or 7 (when held online)
CPD/L/14/2017	1A	PIC/S Requirements for Internal and External Auditing	14
CPD/L/15/2017	1A	Data Integrity and Quality Metrics	14
CPD/L/16/2017	1A	Solid Dosage Manufacturing	14
CPD/L/17/2017	1A	Current and Future Requirements for Technology Transfer and Scale Up	14
CPD/L/04/2018	1A	Current Trends: Updates to the PIC/S CGMPs (V14) and Other Industry Initiatives	14
CPD/L/02/2019	1A	Cleaning Validation- Current best practices and new EU requirements for Health Based Exposure Limits (HBELs)	14
CPD/L/04/2019	1A	Computer System Validation - Applying Current Best Practices and PIC/S Guidelines	14
CPD/L/10/2019	1A	Current Requirements for Supply Chain Integrity and Supplier Assurance Programs (two days)	7 for each day
CPD/L/01/2020	1A	Live Online GMP Training - Development of Control Strategies and Process Validation	7
CPD/L/02/2021	1A	Live Online GMP Training - Facilities & Critical Utilities – Risk-Based Design, Construction, Commissioning, Validation & Qualification	7
CPD/L/03/2021	1A	Live Online GMP Training - Current and Future GMP Requirements for Contamination Control Strategies (CCS)	7
CPD/L/05/2021	1A	Live Online GMP Training: QbD and Process Validation - Best practices for application of science and risk-based practices to development and validation	14

Name of Training Provider		(1) The Hong Kong Institute of Biotechnology Limited	
CPD/L/02/2022	1A	Practical Interpretation of PIC/S Annex 1	14
CPD/L/01/2023	1A	Live GMP Training Workshop: Advances in Microbiology Quality Assurance and Contamination Control Strategies	14
CPD/L/05/2023	1A	Industry Best Practice and Importance of a Quality and Compliance Culture	14

II. Category 1 Activities organized by or associated with OVERSEAS organizations or training providers-

Name of Organization	(1) Drug Information Association (DIA)		
Continuing Development Activity	**Category**	**CPD hours**	**Remarks**
Relevant face-to-face and on-line courses	1A	10x IACET CEUs (if specified); or on-line course duration; or actual training hours excluding registration, breakfast, lunch and breaks	The program catalogue, overview or agenda should be kept as documentary proof of program duration or IACET CEUs granted.
Relevant workshop, conference and forum	1B	10x IACET CEUs (if specified); or Actual contact hours excluding registration, breakfast, lunch and breaks	
DIA publications e.g. Global Forum, Therapeutic Innovation & Regulatory Science (TIRS) and Drug Information Journal	1C	Number of actual hours spent on reading the reference materials	Can claim up to a maximum of 6 CPD hours per year accumulative from Category 1C and 2C

Name of Organization	(2) European Compliance Academy (ECA)		
Continuing Development Activity	**Category**	**CPD hours**	**Remarks**
All GMP webinars	1A	1.5 hours per webinars	
All GMP courses	1A	Actual training hours excluding registration, breakfast, lunch and breaks	The program catalogue, overview or agenda should be kept as documentary proof of program duration.
All GMP Conferences	1B	Actual contact hours excluding breakfast, lunch and breaks	
All GMP guidelines available in ECA website and database	1C	Number of actual hours spent on reading the reference materials	Can claim up to a maximum of 6 CPD hours per year accumulative from Category 1C and 2C

Name of Organization	(3) International Society for Pharmaceutical Engineering (ISPE)		
Continuing Development Activity	**Category**	**CPD hours**	**Remarks**
Relevant webinars	1A	Total course duration	The program catalogue, overview or agenda should be kept as documentary proof of program duration or ISPE CEUs granted.
Relevant classroom training courses	1A	10x ISPE CEUs	
Relevant conferences and annual meeting	1B	Actual contact hours excluding registration, breakfast, lunch and breaks	
All guidance documents, handbooks and papers published by ISPE	1C	Number of actual hours spent on reading the reference materials	Can claim up to a maximum of 6 CPD hours per year accumulative from Category 1C and 2C

Name of Organization	(4) Parenteral Drug Association (PDA)		
Continuing Development Activity	**Category**	**CPD hours**	**Remarks**
Relevant face-to-face courses under training or online training	1A	10x ACPE CEUs (if specified); or on-line course duration; or actual training hours excluding registration, breakfast, lunch and breaks	The program catalogue, overview or agenda should be kept as documentary proof of program duration or ACPE CEUs granted.
Relevant conferences, workshops and annual meetings	1B	Actual contact hours excluding breakfast, lunch and breaks	
All PDA Technical Reports, PDA Technical Books and PDA Journal of Pharmaceutical Science & Technology	1C	Number of actual hours spent on reading the reference materials	Can claim up to a maximum of 6 CPD hours per year accumulative from Category 1C and 2C

Name of Organization	(5) Pharmaceutical Inspection Co-operation Scheme (PIC/S)		
Continuing Development Activity	**Category**	**CPD hours**	**Remarks**
PIC/S publications such as guidelines and guidance documents for industry	1C	Number of actual hours spent on reading the reference materials	Can claim up to a maximum of 6 CPD hours per year accumulative from Category 1C and 2C

Name of Organization	(6) The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)		
Continuing Development Activity	**Category**	**CPD hours**	**Remarks**
All quality guidelines	1C	Number of actual hours spent on reading the reference materials	Can claim up to a maximum of 6 CPD hours per year accumulative from Category 1C and 2C

Name of Organization	(7) World Health Organization (WHO)		
Continuing Development Activity	**Category**	**CPD hours**	**Remarks**
WHO Technical Report Series of relevant GMP topics	1C	Number of actual hours spent on reading the reference materials	Can claim up to a maximum of 6 CPD hours per year accumulative from Category 1C and 2C

Name of Training Provider		(8) SeerPharma (Singapore) Pte Ltd	
Course Code	**Category**	**Title of CPD Training Programme**	**CPD Hour(s)**
CPD/O/01/2021	1A	GMP – What You Need to Know	14
CPD/O/02/2021	1A	Quality Risk Management	14
CPD/O/03/2021	1A	Product Quality Review – Principles and Practices	14
CPD/O/04/2021	1A	Cleaning Validation	14
CPD/O/05/2021	1A	Process Validation	14
CPD/O/06/2021	1A	Validation – A Roadmap to Getting It Right First Time	14
CPD/O/07/2021	1A	Managing Internal Audits and External Audits	14
CPD/O/08/2021	1A	Solid Dose Manufacturing	14
CPD/O/09/2021	1A	Computer Systems for Regulated Environment and Data Integrity	14
CPD/O/10/2021	1A	Supply Chain Management and Supplier QA Program	14
CPD/O/11/2021	1A	Root Cause Analysis and CAPA	14
CPD/O/12/2021	1A	Behavioural Good Manufacturing Practice – Minimising Human Errors	14

List of approved Continuing Professional Development Activities (for Secondary Packaging Manufacturers)

The following tables list out the Continuing Professional Development ("CPD") activities approved by the Pharmacy and Poisons (Manufacturers Licensing) Committee for Authorized Persons ("APs") for secondary packaging manufacturers (i.e. Quality Assurance Officers) and Persons-in-charge of secondary packaging.

Please refer to the "Guidance on Qualification, Experience and Training Requirements for Authorized Persons and Other Key Personnel of Licensed Manufacturers in Hong Kong" for details of the CPD requirements and the classification of Category 1 and Category 2 Activities.

Please be reminded that topics of the training enrolled by Quality Assurance Officers and Persons-in-charge of secondary packaging should be relevant to their role and duties with respect to the types of manufacturing operations undertaken by the secondary packaging manufacturers for whom they work.

CPD training topics relevant to the role and duties of an AP for Secondary Packaging Manufacturers (i.e. Quality Assurance Officer) include, but are not limited to:

a. Pharmaceutical law and administration in Hong Kong
b. Role and professional duties of an AP
c. Quality management systems
d. Quality risk management
e. PIC/S GMP Guide and Annexes
f. Pharmaceutical packaging
g. Warehousing
h. Registration of pharmaceutical products.

CPD training topics relevant to the role and duties of Person-in-charge of Secondary Packaging include, but are not limited to:

a. Quality management systems
b. Quality risk management
c. PIC/S GMP Guide and Annexes
d. Pharmaceutical packaging
e. Warehousing.

I. Category 1 Activities organized by LOCAL training providers-

Name of Training Provider		(1) The Hong Kong Institute of Biotechnology Limited	
Course Code	**Category**	**Title of CPD Training Programme**	**CPD Hour(s)**
CPD/L/10/2019	1A	Current Requirements for Supply Chain Integrity and Supplier Assurance Programs (two days)	7 for each day

Name of Training Provider		(2) The Pharmaceutical Distributors Association of Hong Kong Limited	
Course Code	**Category**	**Title of CPD Training Programme**	**CPD Hour(s)**
CPD/L/08/2019	1A	Optimization of Secondary Packaging Process & Warehouse Management	4
CPD/L/09/2019	1A	Pharmaceutical Labelling Requirement & Legal Aspect of Secondary Packaging*	4
CPD/L/09/2021	1A	Pharmaceutical Warehouse and Cold Chain Management in Secondary packaging	8
CPD/L/03/2022	1A	Internal Audit & Control of Non-conformance in Secondary Packaging	4
CPD/L/04/2022	1A	Staff Training & Competency Assessment in Secondary Packaging	4
CPD/L/05/2022	1A	Change Control & Risk Assessment in Secondary Packaging	4
CPD/L/03/2023	1A	Temperature Mapping for warehouse in Secondary Packaging: Principles, Practices, and Compliance	4
CPD/L/04/2023	1A	Pest Management for warehouse in in Secondary Packaging: Principles, Practices, and Compliance	4

** The CPD hours would only be awarded one-off on completion of this course and no CPD hours would be awarded upon repeated attendance thereafter.*

Name of Training Provider		(3) The Pharmaceutical Society of Hong Kong Limited	
Course Code	**Category**	**Title of CPD Training Programme**	**CPD Hour(s)**
CPD/L/01/2018	1A	Pharmaceutical Law & Administration in Hong Kong*	12
CPD/L/02/2018	1A	Fundamental of PIC/S GMP related to Secondary Packaging	8
CPD/L/03/2018	1A	Fundamental of Pharmaceutical Packaging	7
CPD/L/05/2019	1A	Corrective Action and Preventive Action	3
CPD/L/06/2019	1A	Pharmaceutical Warehouse Management and Temperature Mapping	3
CPD/L/07/2019	1A	Deviation and Change Control	3
CPD/L/02/2023	1A	Good Distribution Practice and Management of Secondary Packaging Facilities	7

** The CPD hours would only be awarded one-off on completion of this course and no CPD hours would be awarded upon repeated attendance thereafter.*

Name of Training Provider		(4) Pharmaceutical Management Science Association Limited	
Course Code	**Category**	**Title of CPD Training Programme**	**CPD Hour(s)**
CPD/L/10/2021	1A	GMP Documentation and Record Control	4
CPD/L/11/2021	1A	Introduction to Quality Risk Management in the Pharmaceutical Industry	4

II. Category 1 Activities organized by or associated with OVERSEAS organizations or training providers-

Name of Organization	(1) Drug Information Association (DIA)		
Continuing Development Activity	**Category**	**CPD hours**	**Remarks**
Relevant face-to-face and on-line courses	1A	10x IACET CEUs (if specified); or on-line course duration; or actual training hours excluding registration, breakfast, lunch and breaks	The program catalogue, overview or agenda should be kept as documentary proof of program duration or IACET CEUs granted.
Relevant workshop, conference and forum	1B	10x IACET CEUs (if specified); or Actual contact hours excluding registration, breakfast, lunch and breaks	
DIA publications e.g. Global Forum, Therapeutic Innovation & Regulatory Science (TIRS) and Drug Information Journal	1C	Number of actual hours spent on reading the reference materials	Can claim up to a maximum of 3 CPD hours per year accumulative from Category 1C and 2C

Name of Organization	(2) European Compliance Academy (ECA)		
Continuing Development Activity	**Category**	**CPD hours**	**Remarks**
All GMP webinars	1A	1.5 hours per webinars	
All GMP courses	1A	Actual training hours excluding registration, breakfast, lunch and breaks	The program catalogue, overview or agenda should be kept as documentary proof of program duration.
All GMP Conferences	1B	Actual contact hours excluding breakfast, lunch and breaks	
All GMP guidelines available in ECA website and database	1C	Number of actual hours spent on reading the reference materials	Can claim up to a maximum of 3 CPD hours per year accumulative from Category 1C and 2C

Name of Organization	(3) International Society for Pharmaceutical Engineering (ISPE)		
Continuing Development Activity	**Category**	**CPD hours**	**Remarks**
Relevant webinars	1A	Total course duration	The program catalogue, overview or agenda should be kept as documentary proof of program duration or ISPE CEUs granted.
Relevant classroom training courses	1A	10x ISPE CEUs	
Relevant conferences and annual meeting	1B	Actual contact hours excluding registration, breakfast, lunch and breaks	
All guidance documents, handbooks and papers published by ISPE	1C	Number of actual hours spent on reading the reference materials	Can claim up to a maximum of 3 CPD hours per year accumulative from Category 1C and 2C

Name of Organization	(4) Parenteral Drug Association (PDA)		
Continuing Development Activity	**Category**	**CPD hours**	**Remarks**
Relevant face-to-face courses under training or online training	1A	10x ACPE CEUs (if specified); or on-line course duration; or actual training hours excluding registration, breakfast, lunch and breaks	The program catalogue, overview or agenda should be kept as documentary proof of program duration or ACPE CEUs granted.
Relevant conferences, workshops and annual meetings	1B	Actual contact hours excluding breakfast, lunch and breaks	
All PDA Technical Reports, PDA Technical Books and PDA Journal of Pharmaceutical Science & Technology	1C	Number of actual hours spent on reading the reference materials	Can claim up to a maximum of 3 CPD hours per year accumulative from Category 1C and 2C

Name of Organization	(5) Pharmaceutical Inspection Co-operation Scheme (PIC/S)		
Continuing Development Activity	**Category**	**CPD hours**	**Remarks**
PIC/S publications such as guidelines and guidance documents for industry	1C	Number of actual hours spent on reading the reference materials	Can claim up to a maximum of 3 CPD hours per year accumulative from Category 1C and 2C

Name of Organization	(6) The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)		
Continuing Development Activity	**Category**	**CPD hours**	**Remarks**
All quality guidelines	1C	Number of actual hours spent on reading the reference materials	Can claim up to a maximum of 3 CPD hours per year accumulative from Category 1C and 2C

Name of Organization	(7) World Health Organization (WHO)		
Continuing Development Activity	**Category**	**CPD hours**	**Remarks**
WHO Technical Report Series of relevant GMP topics	1C	Number of actual hours spent on reading the reference materials	Can claim up to a maximum of 3 CPD hours per year accumulative from Category 1C and 2C