## Module Synopsis and Duration for PCP TnP Advanced Biopharmaceuticals Manufacturing

| No | Module Title | Duration (hr) | Outline |
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| 1 | Follow Good Manufacturing Practices | 8 | Basic knowledge & skills to follow standard operating procedures & contamination control procedures, report and record abnormalities when carrying out their tasks in a manufacturing or process environment. |
| 2 | Apply Continuous Process Improvement Techniques | 15 | Skills and knowledge in applying continuous process improvement techniques and be able to put it into practice at their workplaces. |
| 3 | Apply Process Quality Control Techniques | 30 | Covers application of basic techniques for controlling the quality of materials and services in a process plant environment. Personnel are required to prepare to examine and assess quality; monitor and control quality; report on status of quality and perform quality housekeeping. |
| 4 | Apply Safety in Process Plant | 21 | Covers the skills and knowledge required by the worker to be able to accurately identify process occupational health and safety hazards, and assess risk in a process environment, as well as follow safety instructions. |
| 5 | Operate in Controlled Clean Room Environment | 40 | Covers knowledge and skills in to operate in a clean room environment to initially prepare for work activity, to maintain the clean room environment in operation, and reinstate the clean room environment post operations. |
| 6 | Apply Data Analytics | 21 | Covers knowledge and skills to gather data and organize the data for analysis; ability to build dashboards using PivotTables and PivotChart; proficiency in using tools for generating different scenarios and aiding decision making. The module also includes developing a dashboard that answers the problem question, learn to organize and plan the items in a dashboard and provide insights, KPI reporting and informed decision making. |
| 7 | Apply Process Analytical Technology | 21 | Evaluate, develop, implement, validate and perform life cycle maintenance on specific PAT applications used in GxP; Understand functionalities and measurement principles; Operations of PAT on-line equipment, including troubleshooting, optimisation and cleaning; Use of outliers diagnostics, periodic verification, etc. |
| 8 | Apply Manufacturing Technologies in a Regulated Environment | 30 | Covers the ability to apply the principles of current good manufacturing practices (cGMP) to pharmaceutical manufacturing technologies. Personnel are required to apply the principles of quality by design, risk management and continuous improvements as per the ICH (International |

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| | | | Conference on Harmonisation) guidelines Q8, Q9 and Q10 to the manufacture of pharmaceuticals and within the industry best practice guidelines of Baseline Guide 5 and Good Automated Manufacturing Practice (GAMP). |
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| | **Biologics Track** | | |
| 9 | Operate Tangential Flow Filtration Process Equipment | 18 | Covers knowledge and skills to setup tangential flow filters as well as perform integrity testing, basic operations on tangential flow filtration equipment. The learner will also have the basic knowledge and skill to reinstate tangential flow filtration equipment. |
| 10 | Operate Inoculation and Fermentation Reactors | 40 | Covers knowledge and skills to prepare and perform fermenter set-up, fermentation medium sterilization, fermenter inoculation, fermentation monitoring and control, cell harvesting, biohazard waste treatment for disposal and fermenter cleaning. |
| 11 | Operate Chromatography Process Equipment | 18 | Covers knowledge and skills to setup chromatography process equipment as well as perform packing testing, basic operations on chromatography equipment. The learner will also have the basic knowledge and skill to reinstate chromatography equipment. |
| 12 | Operate Single-Use Technologies | 18 | Covers the skills and knowledge required by people to operate single use technology which includes preparing single use equipment for upstream process operations; performing sterile connection and disconnection and validating single use equipment. |
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| | **Pharmaceuticals Track** | | |
| 13 | Operate Tangential Flow Filtration Process Equipment | 18 | Refer to no. 9 |
| 14 | Apply Continuous Manufacturing Techniques | 16 | Covers continuous manufacturing of high value chemicals and the differences with traditional batch processes, which include:<br>· Throughput of continuous process<br>· Definition of "a batch" in continuous manufacturing<br>· Common continuous unit operations<br>· Safety considerations of continuous operations<br>· Control and automation considerations of continuous operations<br>· Case studies |
| 15 | Illustrate a Lifecycle Plan for a Manufacturing Facility | 30 | Covers the ability to apply pharmaceutical science and engineering concepts to define the life cycle phases associated with the design and operation of a typical pharmaceutical facility, including conceptual material balances, site master-planning and detailed design, construction, commissioning and qualification. Personnel are also required describe |

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| | | | an overview of operation & maintenance and continuous improvements through to the stage of plant retirement and decommissioning. |
| 16 | Operate Single-Use Technologies | 18 | Refer to no. 12 |
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| | **Cell & Gene Therapy Track** | | |
| 17 | Apply Aseptic Cell Culture Techniques | 40 | Covers the knowledge and aseptic techniques to handle cell cultures – both microbial and mammalian which include how to maintain cell cultures in a pure state during the upstream and fermentation stages. It also includes the competency of how to identify and maintain requirements for aseptic environmental and processing conditions as well as to maintain viral clearance barriers during all stages of manufacturing. |
| 18 | Illustrate a Lifecycle Plan for a Manufacturing Facility | 30 | Refer to no. 15 |
| 19 | Operate Single-Use Technologies | 18 | Refer to no. 12 |