

PAT from Development to Real Time Release Testing
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Course Outline

This course is focused on welcoming newcomers and seasoned veterans to the Annual IFPAC conference and covers several topics that are part of the conference.

This year's course will follow a path from development to Advanced Pharmaceutical Manufacturing and Real Time Release Testing for the first time.

Part	Time (mins)	Topic
Introduction	15	PAT Definition, Timeliness, PAT Guidance, key ideas from proposed USP General Chapter <1037>, PAT Scientific Community,
PAT in Development	20	Process knowledge Materials Characterization When to Deploy -Advantages & Disadvantages (company tool box) Integration of PAT & QbD
	20	Regulatory Considerations Communication with a regulatory agency. How PAT is integrated in ICH Q8 & Q9, ICH Q12 Emerging Technologies & Graduation
PAT Implementation & Applications	50	Process measurement instrumentation must be integrated. PAT & Sampling (Fundamental Sampling Principle, Lot Dimensionality Transformation) Role of Chemometrics USP Chapters
Opportunities in API manufacturing and biologics	30	API Flow Chemistry & Reaction Monitoring Gene & Cell Therapy Monitoring Machine learning, AI
Real Time Release Testing & Advanced Manufacturing	30	Integration with Quality System Real Time Release Testing PAT within Advanced Pharm Manufacturing