



Process Analytical Technology

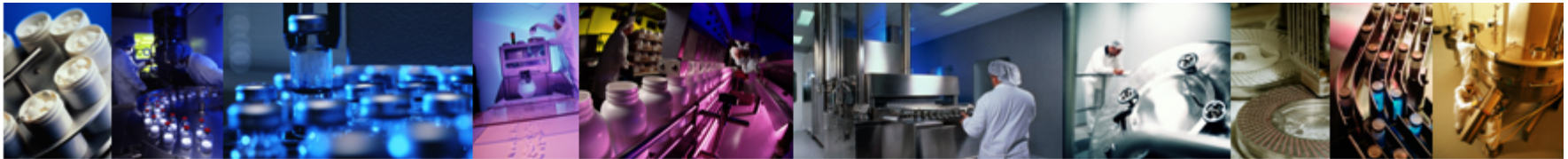
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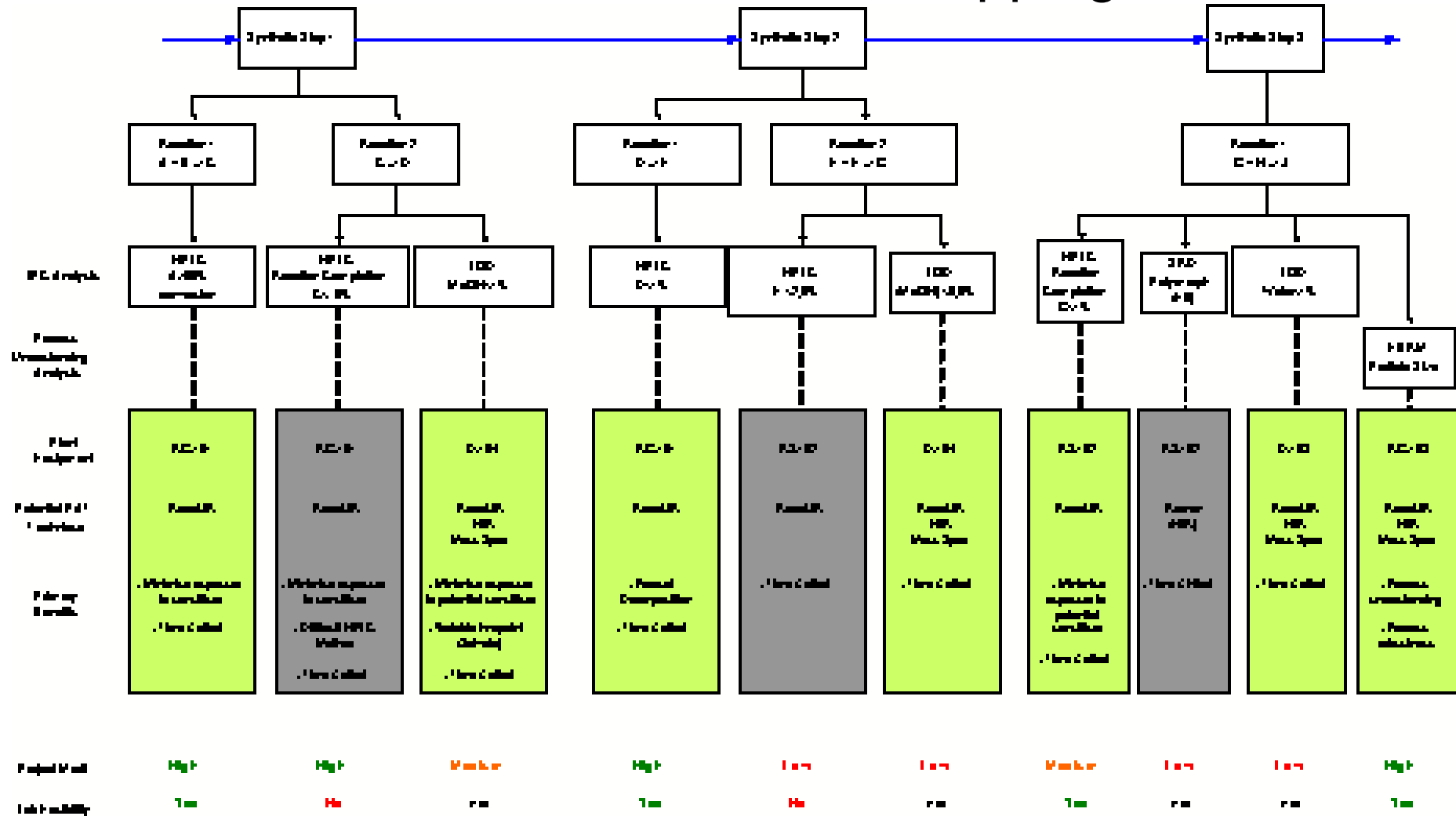


Agenda

9:00 - 10:00	Sample Exam Questions
10:00 - 10:15	Team Exercise 1: Process Map Introduction
10:15 - 11:00	Team Exercise 1: Process Map
11:00 - 11:10	Break
11:10 - 11:40	Team Exercise 1: Present to Group
11:40 - 12:00	Exercise 2: Sampler Location Introduction
12:00 - 13:00	Lunch
13:00 - 13:40	Exercise 2: Sampler Location <i>(Present, time permitting)</i>
13:40 - 14:00	Exercise 3: Project Implementation Introduction
14:00 - 14:30	Exercise 3: Project Implementation Strategy
14:30 - 15:00	Exercise 3: Present to Group
15:00 - 16:00	Assignment Q&A Opportunity



Exercise 1: Process Mapping

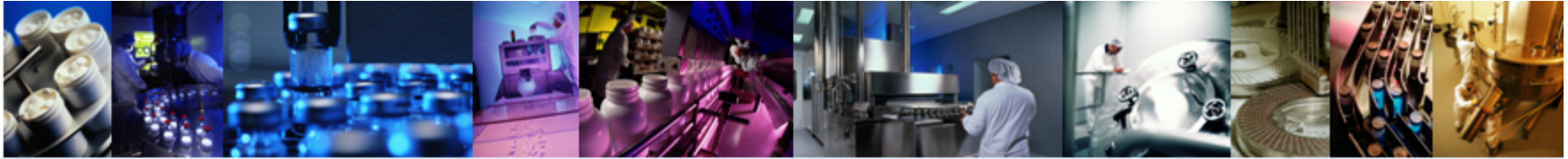




Exercise 1: Process Mapping

Task: For your process perform the following...

1. Map the individual unit operations
2. Identify quality attributes
3. Identify current off-line analytical testing
4. List potential PAT techniques
5. List benefits of adopting PAT
6. Estimate ease of successfully implementing each PAT

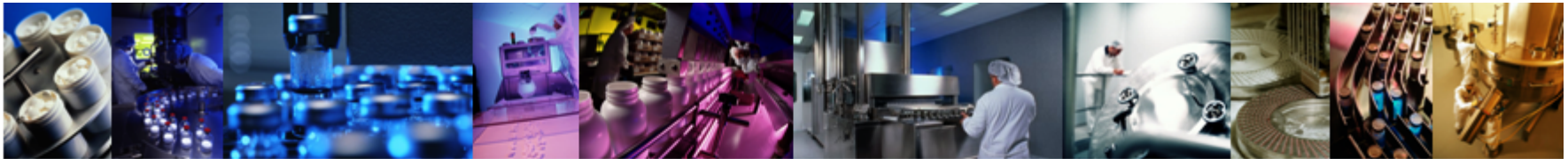


Exercise 2: Sampler Location

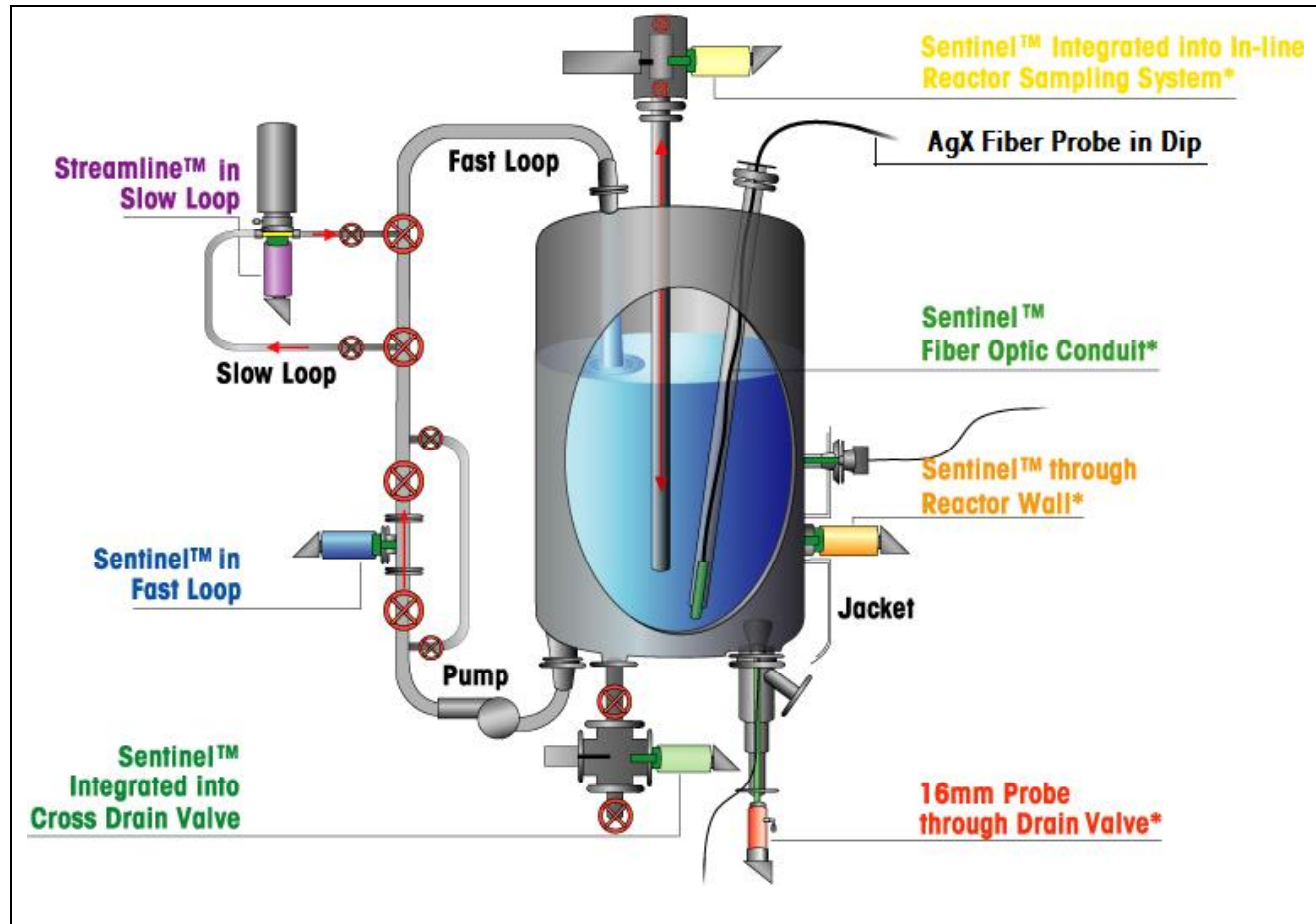
In-line > On-line > At-line > Off-line

Where in this hierarchy an application actually lies will depend on a number of factors, including but not limited to the following:

- Analytical technology employed
- Process temperature
- Chemical compatibility
- Probe / analyser fouling
- Available space in plant
- Suitability of fibre optics
- Acceptability of destructive analysis



Exercise 2: Sampler Location





Example On-line - Laser Diffraction

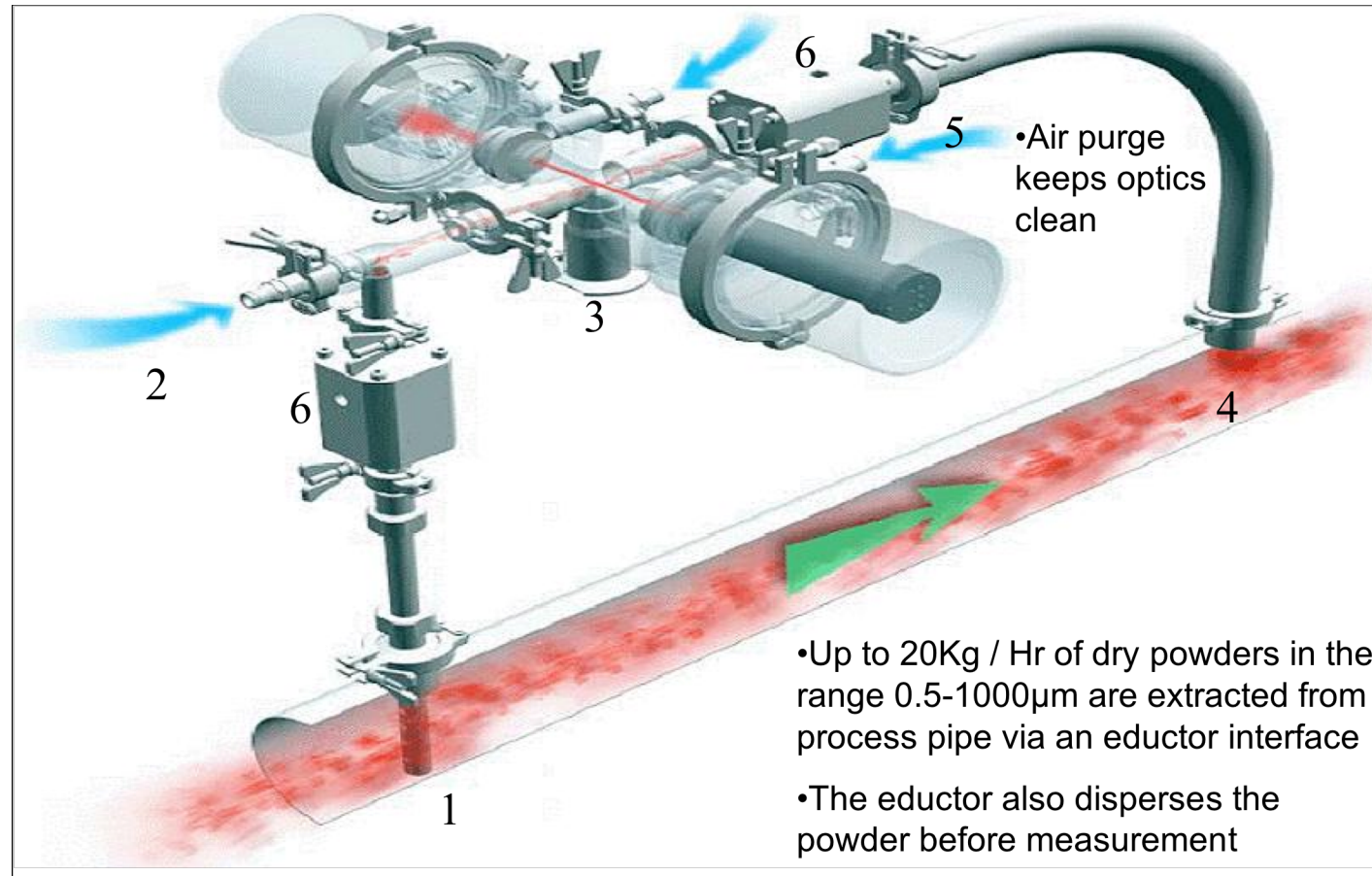


Figure: Malvern on-line bypass loop particle analyser system.



Example In-line - Laser Diffraction

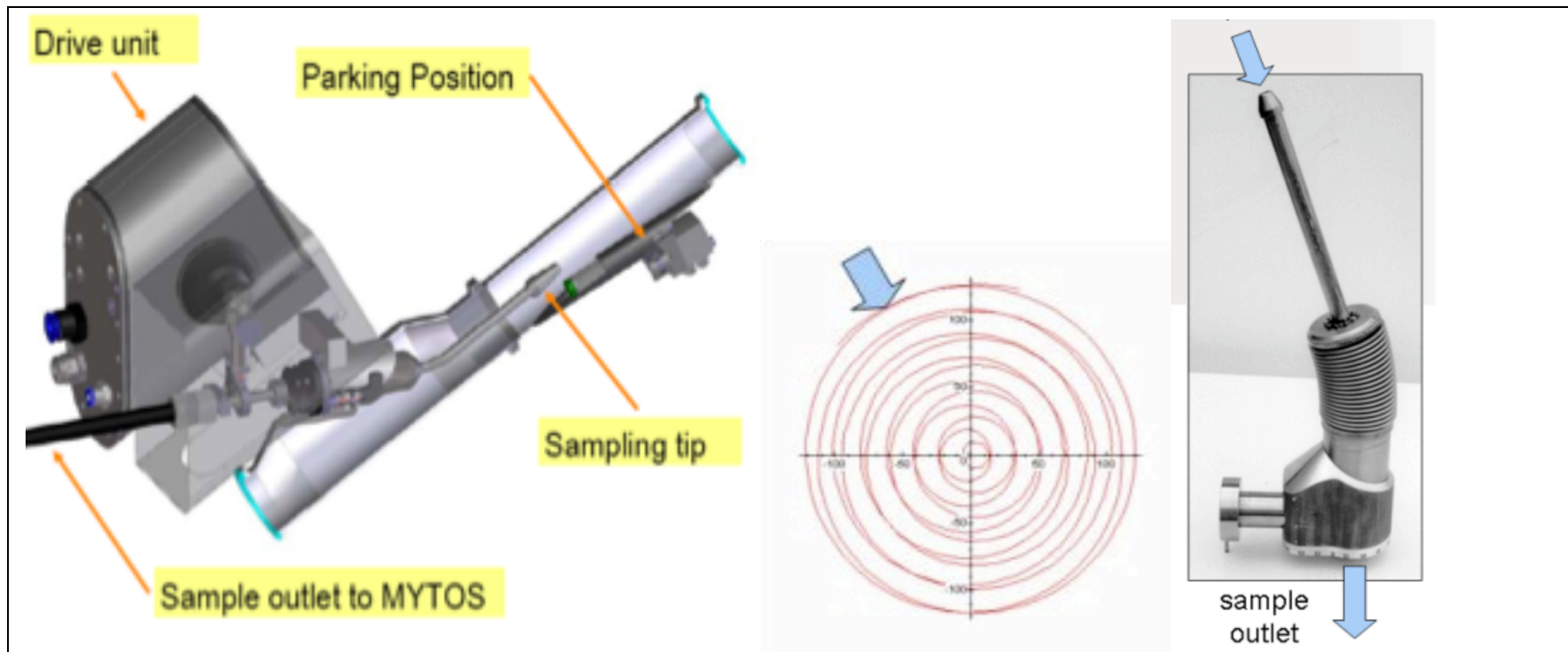


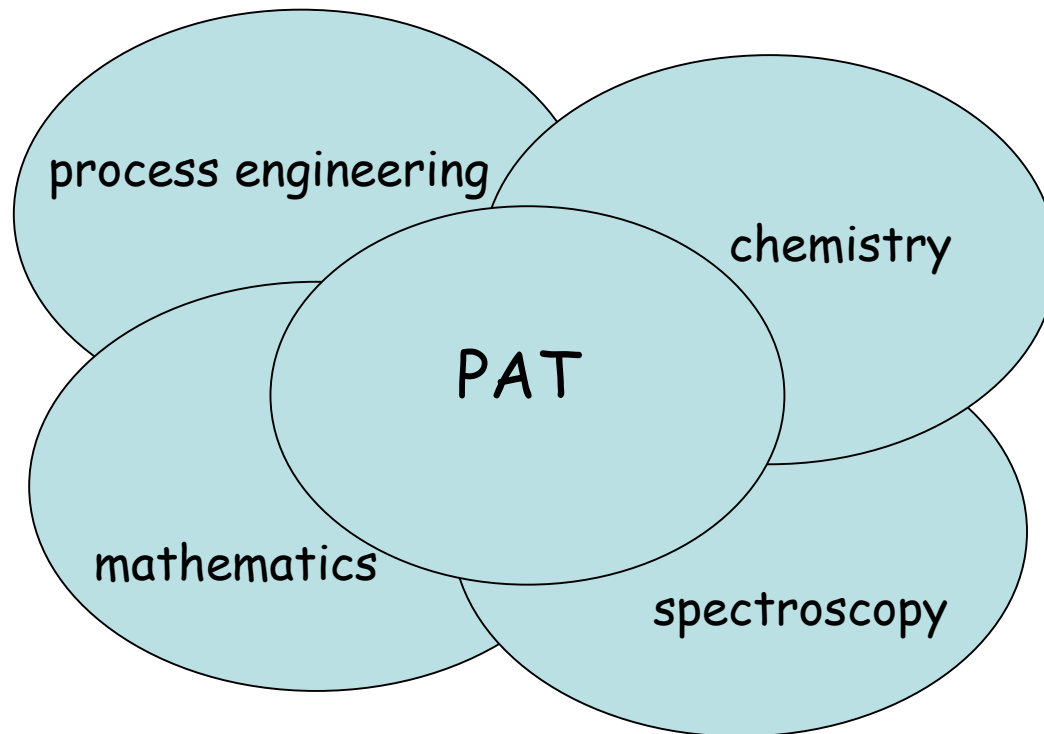
Figure: SympacTec Twister sampling system for use with Mytos particle size analyser.

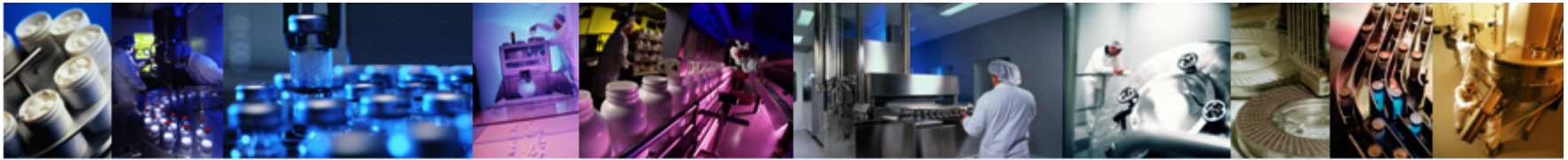
	Near IR	Mid IR	Raman	UV/Vis
Spectral Range (cm-1)	12,800-4,000	4,000-400	4,000-50	105-5,000
Information Content	Bonds with dipole moments. Predominantly O-H, N-H, C-H vibrations, though other bonds may be observed.	Bonds with dipole moments. More info than NIR (i.e. not just O-H, N-H, C-H).	Bonds must contain weak dipole moment (polarisable). Bonds observed are non-polar.	Absorption process resulting from electron transitions.
Polymorph Detection?	☹️	☹️ ☹️	😊😊😊	☹️
Spectrum Interpretation	☹️ Spectra broad + overlapping. Chemometrics essential	😊 Spectra interpreted by functional groups.	😊 Spectra interpreted by functional groups.	☹️ Broad peaks. Poor chemical discrimination.
Aqueous Systems?	☹️	☹️ ☹️	😊	😊
Fibre Optic Interface?	😊	☹️ ☹️	😊	☹️
Cost Rating	€ €	€ € €	€ € € €	€



Exercise 3: Project Implementation

Establish Cross Functional Team:





Exercise 3: Project Implementation

What are the major steps required to bring a PAT project from concept to practice?
Organise a strategy and identify subject matter experts required.

Build a correlation

Gather off-line data

Validate a correlation

Gather raw PAT data

Computer System Validation

Impact on regulatory filing

Software tools

Select an analyser vendor

Data management