

Case Study Highlights



Case Study: Cell Culture Optimization Through Respiratory Gas Monitoring



SITUATION

- Process understanding and optimization of mammalian cell cultures is reliant on online and offline measurements
- Two projects were initiated to evaluate the online process mass spectrometry
- One of the cell lines was a GS-CHO producing IgG4 monoclonal antibody (mAb)

SOLUTION

- Precision of the Thermo Scientific™ [Prima BT Bench Top Mass Spectrometer](#) was 50x greater for both CO2 and O2, and drift between calibration was eliminated
- When monitoring 12 fermenters the price of the mass spectrometer was equivalent to the low performance sensors

VALUE DELIVERED



- **High precision and speed analysis**



- **Better process understanding**
 - RQ could be seen and corrective action taken



- **Cost savings**
 - Expensive media and labor hours were not wasted on failed fermentation batches
 - The inclusion of methanol and ethanol analysis was realized at no extra cost

Case Study: Rapid Biologic Drug Product Identification



SITUATION

- Per FDA/GMP compliance requirements, customers must ID both bulk drug substance and final product
- Current technologies like peptide mapping are difficult and time consuming
- Many customers must send samples to centralized labs

SOLUTION

- Point of use solutions to replace existing testing workflows
- Thermo Scientific™ [TruScan™ RM Handheld Raman Analyzer with TruTools](#) enables customers to remove the overall burden from QC labs

VALUE DELIVERED



- **From 10 days to 10 minutes**



- **More cost effective**
 - Point-of-use testing without requiring sites to have expensive testing technologies

Case Study: Replacement of GC for Solvent Quantification



SITUATION

- Aqueous mixtures of solvents and water are commonly used in downstream processing of pharmaceutical products
- Current testing requires sending samples to the laboratory for GC analysis

SOLUTION

- Thermo Scientific™ [TruScan™ RM Handheld Raman Analyzer with TruTools](#) has been validated using production lots with results comparable to or superior to GC testing

VALUE DELIVERED



- **From 6 hours to 10 minutes**



- **More cost effective**
 - Point-of-use testing

Case Study: Raw Material ID with Handheld Instrumentation



SITUATION

- Currently samples taken from the manufacturing floor are sent to a centralized lab
- Labs generally have a backlog and products are put on hold until tests are complete
- Pharma industry is looking for faster release from analytical testing



SOLUTION

- Thermo Scientific™ [TruScan™ RM/GP Handheld Raman Analyzer](#) and [microPHAZIR™ RX Analyzer](#) provide point-of-use solutions to replace existing testing workflows
- TruTools allows quantitative models to replace advanced in-process QC tests
- TruTools provides TruScan RM the ability to ID complex materials that handheld instrumentation previously could not perform



VALUE DELIVERED



- **Faster release**



- **No sampling, no queue**

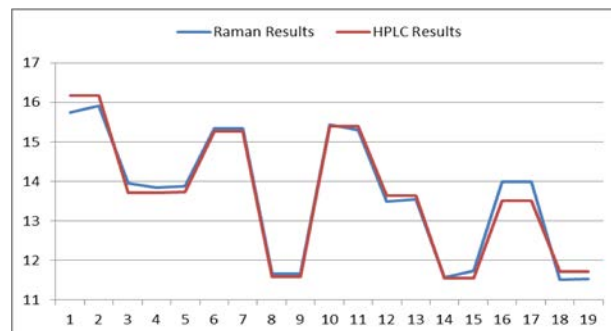
Case Study: API Quantification

SITUATION

- HPLC is currently used for API quantification that takes hours for each inspection
- HPLC creates solvent and disposal waste

SOLUTION

- Thermo Scientific™ [TruScan™ RM Handheld Raman Analyzer with TruTools](#) provides a point-of-use solution with the same results as HPLC
- Increases production throughput



VALUE DELIVERED



- **Faster results**
 - Higher production capability



- **Reduce lab material costs**

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