

PAT Benefits Case



PPAR

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PAT Benefits Case



- 2 buckets for discussion

1. Economic Benefits

2. Regulatory Benefits

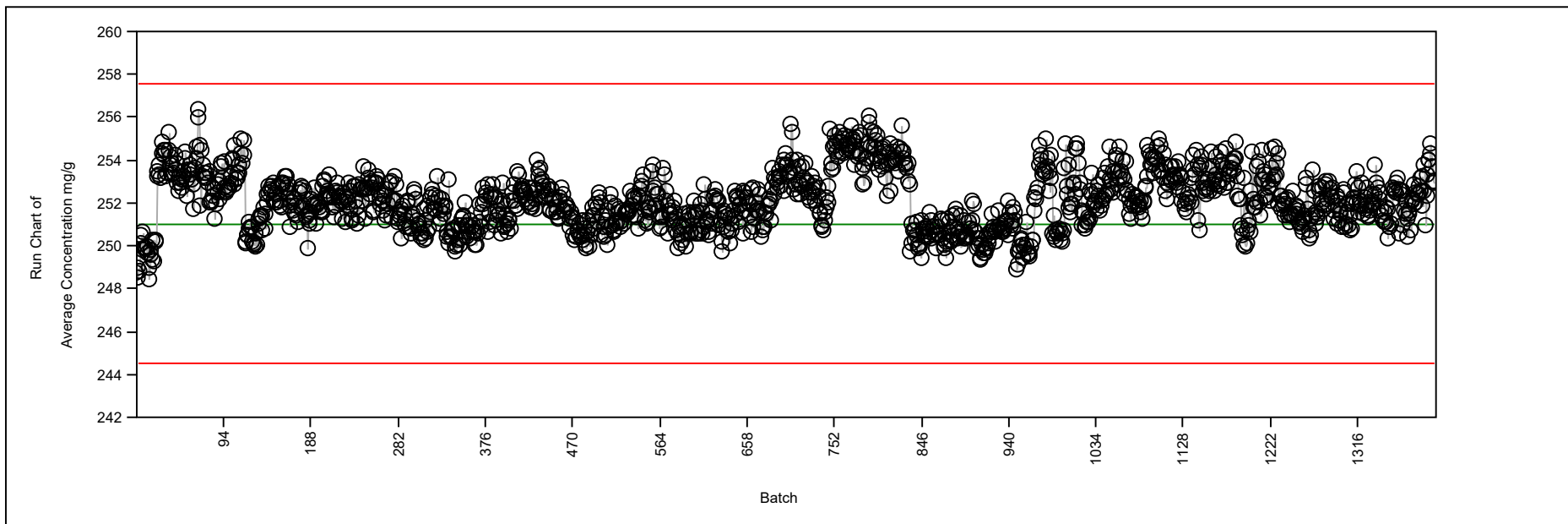
Economic Benefits



○ Merck Examples

1. Tech transfer - \$2MM saving in API costs
2. Process Monitoring - >\$3MM saved using MV fault detection
3. Januvia – 5 years of RTRT
 - 1,399 batches released
 - Tech transfer for second production site

Concentration Data - History



- Average Concentration by batch (mg/g)
- 1,399 Batches plotted (representing nearly 5 years of production)
- Original average and control limits shown –set by first 30 batches produced.

Economic Benefits Q&A



- Business areas expect quantifiable benefits
 - How do you quantify benefits?
 - How many years to show benefits?
 - 1, 2, 5, 10 years?
 - A prerequisite for starting PAT projects?
 - Does six sigma play a role? Rigor level?

Regulatory Benefits Q&A



- Regulatory Benefits post FDA PAT guidance
 - Have benefits materialized?
 - Has the industry capitalized on FDA guidance?
- PAT and QbD
 - Experiences with QbD (PAT) filings?
 - Any regulatory “relief”