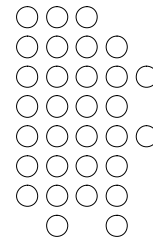


PAT Submissions in OINDP Industry

Session Moderators:

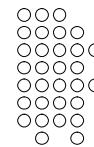
Steve Horhota (BI)
Charles Mader (GSK)



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1

1 Have you submitted new drug applications w/ PAT?



1. No



2. Yes w/ limited PAT



3. Yes w/ significant PAT component

0%

100 Responses

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2

2 Have you submitted post-approval supplements w/ PAT (for manufacturing changes)?



1. No



2. Yes w/ limited PAT



3. Yes w/ significant PAT component

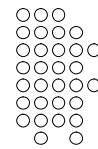
0%

103 Responses

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3

Note for the following slides

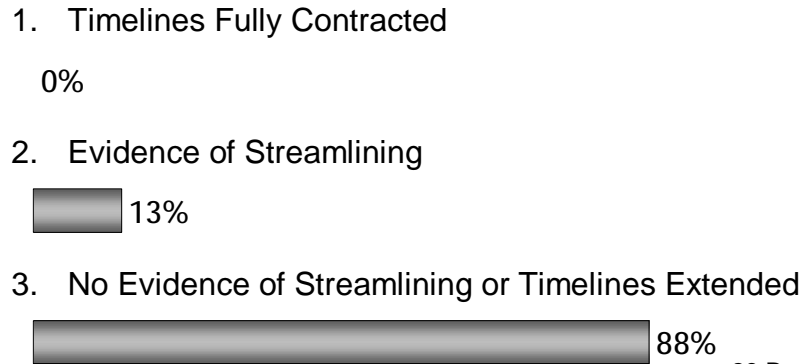
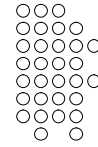


- Since not many PAT submissions have been used for OINDP yet (as shown in the previous slides), the questions and answers on the following slides reflect the audience's understanding and impressions based on the strategic intent to use PAT, as well as on the actual experience with PAT implementation

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3 Has the implementation of PAT streamlined development and approval or burdened it? Are timelines being extended or contracted?

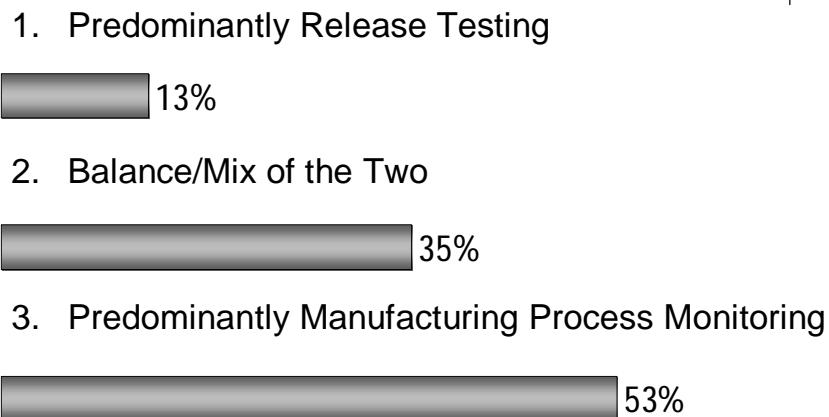
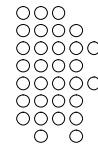


28 Responses

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5

4 How often is PAT used for monitoring manufacturing processes and how often for release testing?



75 Responses

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6

5 Has your use of PAT focused on control of product attributes and/or process parameters?



1. Predominantly Product Attributes



2. Balance/Mix of the Two



3. Predominantly Process Parameters

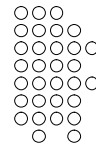


87 Responses

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7

6 Have you found nasal sprays or MDIs or DPIs to be the easiest for application of PAT?



1. Nasal Spray



2. MDI's



In the discussion, it was clarified that nasal solutions are easiest to implement while DPIs might be most likely to implement because they could benefit the most from PAT approaches

3. DPI's

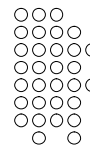


74 Responses

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8

7 Is introduction of PAT incremental and limited or is it applied in a pre-meditated fashion extending to all stages of product development and all operational areas?



1. Limited to Manufacturing



2. Extended to All Levels of Development and Manufacture



3. Limited to Product Development



97 Responses

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9

8 Have you identified (within various stages of product development) specific analytical methods that are useful for PAT applications in the area of OINDP?



1. Yes, identified and implemented



2. Yes, identified but not able to implement



3. Applications limited to manufacturing methods

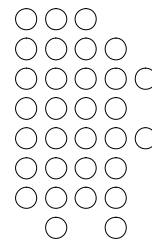


67 Responses

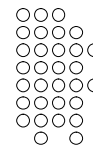
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Highlights from Discussions



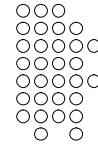
Status



- | PAT is not used much (yet), at least for OINDP

- | For those few PAT that have been submitted
 - | No acceleration timeline
 - | Generally took longer

Barriers



- | Cost
 - | Especially for smaller companies

- | Unclear benefits
 - | Especially short-term
 - | Skepticism about longer-term
 - | What to do with all the PAT data? Where does it help?

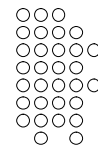
- | Limitations in sensor technology
 - | Especially for low-dose

- | Some uncertainty about regulators' commitment

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Opportunities



- | Unique features of OINDPs
 - | OINDP are “half-device” and dimensional measurement systems are very mature technologies - WE CAN DO THIS NOW

- | Other “PAT-compatible” tests
 - | Gravimetric tests could be used for PAT-type tests
 - | Light obscuration, especially for suspensions

- | Extensive discussions and engagement with FDA
 - | Good learning experience for both sides
 - | Chance for quality discussions as new concepts evolve and develop

- | QbD is perceived to offer more benefit than PAT
- | Better understanding of process (and product)

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