

**Questionnaire for IPAC-RS 2008
Conference Session
*Design Control for Orally Inhaled and
Nasal Drug Products (OINDPs)***

135 attendees participated in the voting

Slide 1



Overview of Device Design Control Session

- European, US and International Medical Device Standards and Regulations for OINDP (Paul Lafferty and Tim Chesworth)
- Interactive Polling Session Current Practices in Device Design Control
- OINDP Development Case Study (Guillaume Brouet)
- Break (3:15-3:45 PM)
- Q&A and Discussion of Survey Outcomes
- Conclusion

Slide 2



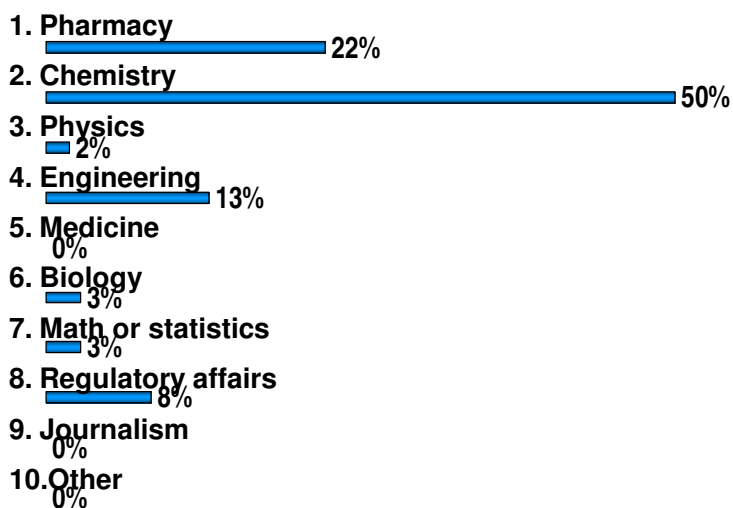
I. Demographics of the Audience

Slide 3



Q1

**What is your main professional training?
(Select ONE)**



Slide 4



Q2

In what sector do you work? (Select ONE)

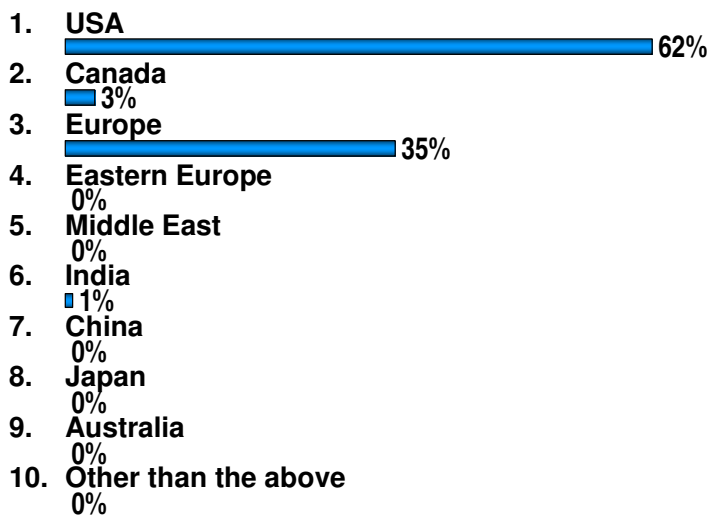


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Q3

In what geographical region do you work? (Select ONE)



Slide 6



Q4

What is your primary area of responsibility? (Select ONE)

1. Design of devices or components for OINDPs
6%
2. Formulation or toxicology studies for OINDPs
4%
3. Analytical testing in support of an OINDP system development
17%
4. Manufacturing processes for OINDPs
6%
5. Clinical trials for OINDPs
0%
6. Preparation of regulatory submissions for OINDPs
14%
7. Regulatory review of the device part of regulatory submissions for OINDPs
5%
8. More than one of the above
40%
9. Academic-type research or consulting related to OINDPs
2%
10. Other
5%

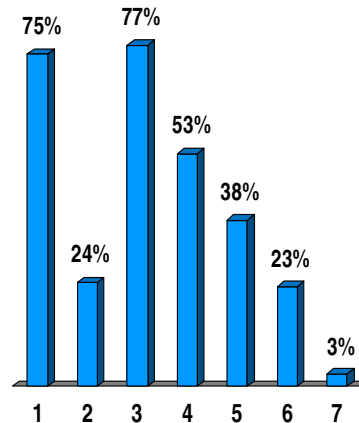
Slide 7



Q5

With what OINDP systems (entire systems or parts of it) have you personally worked (developing, manufacturing, approval, etc) ? (Select ALL that apply)

1. Pressurized metered dose inhalers (pMDIs)
2. Non-pressurized metered liquid inhalers (MLIs)
3. Dry powder inhalers (DPIs) – either reservoir based or unit-dosed
4. Nasal sprays
5. Nebulizers
6. Other novel and exotic OINDPs
7. None of the above

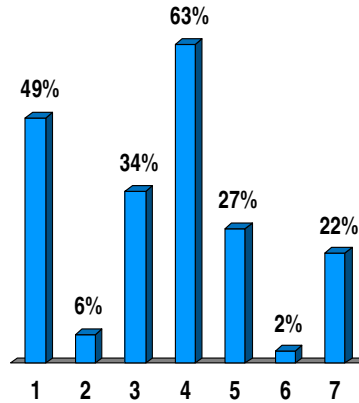


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Q6 With what types of OINDPs do you have experience as a physician, nurse or user (e.g., you or your family member has used for treatment)?
(Select ALL that apply)

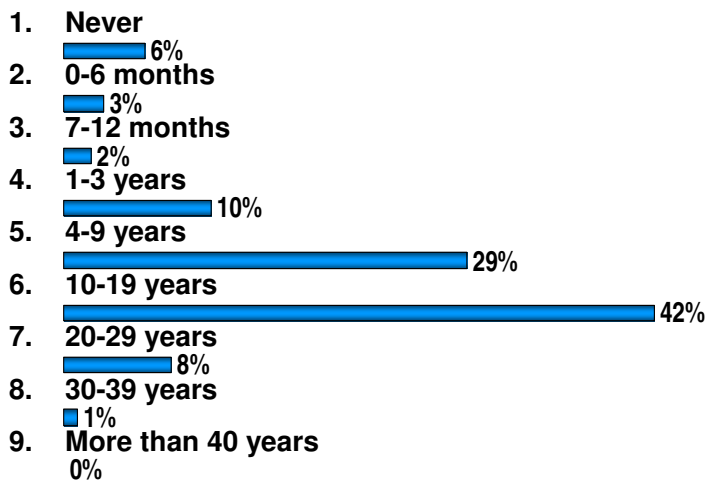
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4. Nasal sprays
5. Nebulizers
6. Other novel and exotic OINDPs
7. None of the above



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Q7 For how long have you worked with OINDP systems (e.g., through development, manufacturing, approval or marketing)?
(Select ONE)



Slide 10

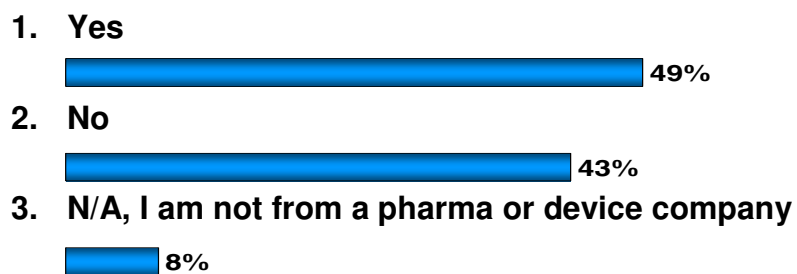


II. Changes Between Clinical Phases 2 and 3 or Their Equivalents

Slide 11



Q8 Do you have experience with a non-trivial change to an OINDP device between clinical trial phases 2 and 3 or their equivalents?
(Select ONE).



Slide 12



Q9 Thinking of one particular example, what was the primary reason for the change?
(Answers on next slide) (Select ONE).

1. Mechanical reliability or robustness of the device (e.g., issues with the dose counter)
2. Manufacturability (e.g., need to optimize the device for high-speed assembly)
3. Changes to the drug product's formulation (which in turn may have changed the leachables profile or other aspects of the formulation-device interaction)
4. Complications during scale-up between phase 2 and 3 (e.g., particle size growth during mixing and filling on the new equipment)
5. Ergonomic: Changes to the device to improve device usability in the hands of a patient (e.g., optimized valve or actuator design)
6. External influences (changes in regulations, results of clinical trials, changes in the market place, change of suppliers of raw materials or components)
7. N/A, I have no experience with a phase 2-to-3 change

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Q9 Thinking of one particular example, what was the primary reason for the change?
(Simplified text) (Select ONE).

1. Mechanical reliability or robustness of the device
 23%
2. Manufacturability
 6%
3. Changes to the drug product's formulation
 6%
4. Complications during scale-up between phase 2 and 3
 5%
5. Ergonomic
 5%
6. External influences
 10%
7. N/A, I have no experience with a phase 2-to-3 change
 45%

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Q10 For the example in the previous question, by how long was the development timeline extended due to the primary change?
(Select ONE).

1. Less than 3 months
 2%
2. 3-6 months
 6%
3. 7-12 months
 14%
4. 1-2 years
 21%
5. 3 or more years
 11%
6. Cancellation of the entire project
0%
7. N/A, because I have no experience with a phase 2-to-3 change
 46%

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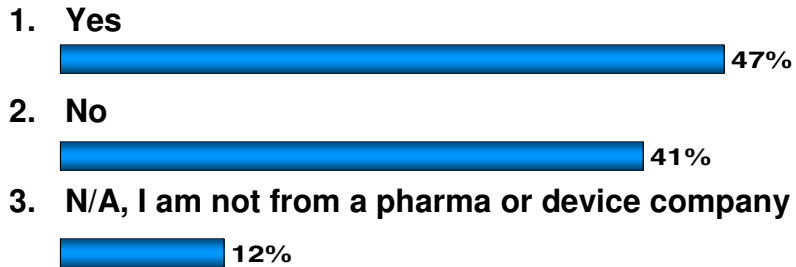
III. Post-Approval Changes

Slide 16



Q11

Do you have experience with a non-trivial change to an OINDP device post-approval? (Select ONE)



Slide 17



Q12 (Answers on next slide)

Thinking of one particular example, what was the primary reason for the change? (Select ONE)


1. Mechanical reliability or robustness of the device (e.g., issues with the dose counter)
2. Manufacturability (e.g., need to optimize the device for high-speed assembly)
3. Changes with the supplier of formulation ingredients
4. Changes with the supplier of device component(s)
5. Changes in raw material suppliers
6. Retroactive changes of regulatory requirements
7. Changed market conditions
8. Ergonomic improvements to the device
9. N/A, I have no experience with a post-approval change

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Q12 (Simplified text)

Thinking of one particular example, what was the primary reason for the change? (Select ONE)

1. Mechanical reliability or robustness of the device
 8%
2. Manufacturability
 6%
3. Changes with the supplier of formulation ingredients
 6%
4. Changes with the supplier of device component(s)
 9%
5. Changes in raw material suppliers
 16%
6. Retroactive changes of regulatory requirements
 2%
7. Changed market conditions
 3%
8. Ergonomic improvements to the device
 5%
9. N/A, I have no experience with a post-approval change
 47%

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Q13 For the example in the previous question, how long did it take to conduct studies to justify the change, obtain regulatory approval and implement the change? (Select ONE)

1. Less than 3 months
 3%
2. 3-6 months
 2%
3. 6-12 months
 7%
4. More than 1 year
 40%
5. Removal of product from the market
0%
6. N/A, I have no experience with a post-approval change
 49%

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IV. Use of ICH Q-8 and Quality by Design (QbD) Principles

Slide 21



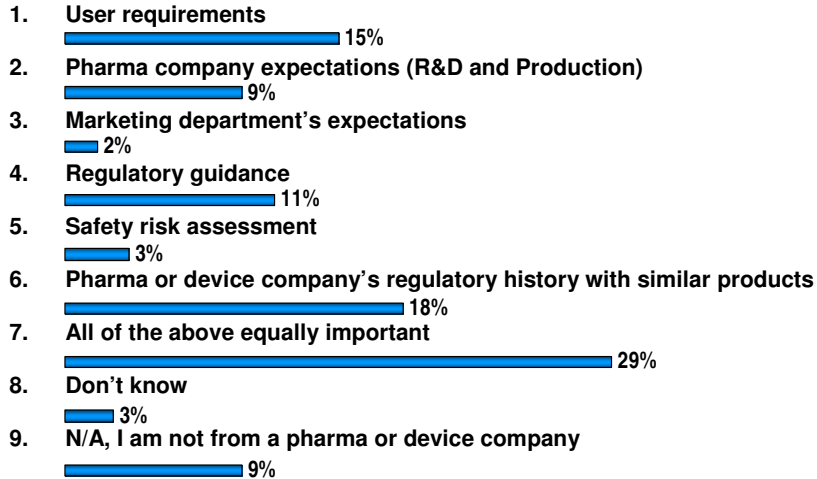
Q14 In your experience, when does the development or selection of an OINDP device (or re-development of a pre-existing device) first cross paths with the development of the formulation?
(Select ONE)

1. **Pre-phase 1**
 38%
2. **Clinical Phase 1**
 15%
3. **Clinical Phase 2a**
 12%
4. **Clinical Phase 2b**
0%
5. **Clinical Phase 3**
 1%
6. **Could be any of the above depending on the circumstances**
 19%
7. **Don't know**
 4%
8. **N/A, I am not from a pharma or device company**
 10%

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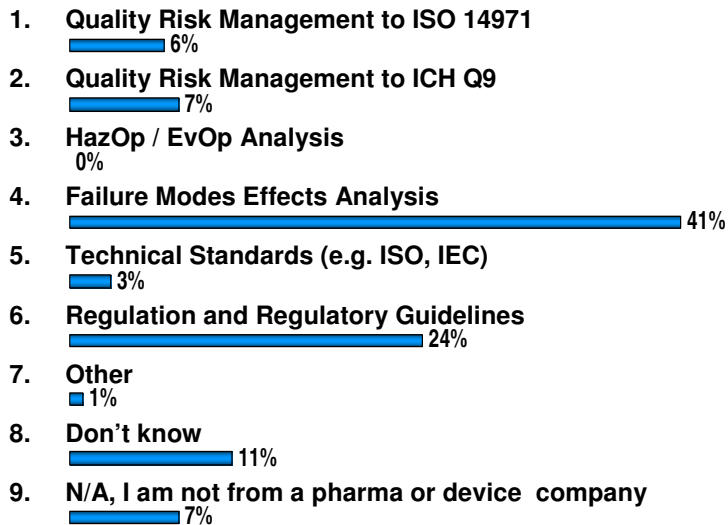
Q15 In your experience, what has been the **MAIN FACTOR** driving the setting of device specifications for an OINDP? (Select ONE)



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Q16 Which of the following tools ***PREDOMINANTLY*** drives product risk reduction in development of the device part of your OINDP? (Select one)



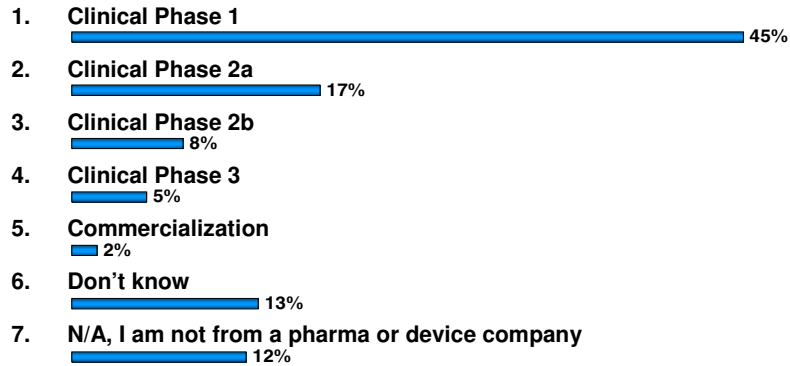
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Q17

Before which phase does your company typically begin integrating risk assessment tools on the device development, re-development or adjustment during an inhaled or nasal drug product development?

(Select the EARLIEST ONE that applies)

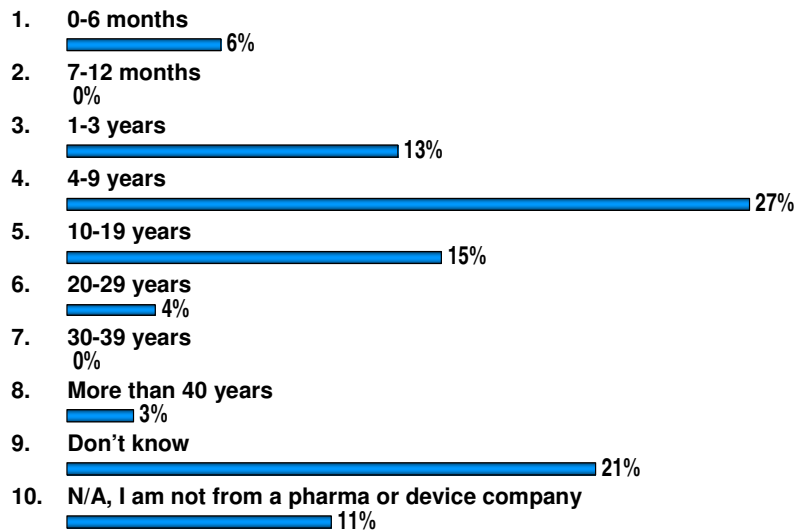


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Q18

How many years has your company been using these and similar tools for device as part of an inhaled or nasal drug product development? (Select ONE)

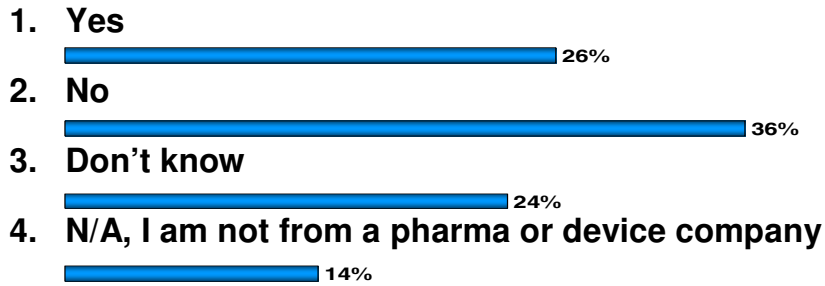


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Q19

Prior to the FDA Quality-by-Design initiative (2004), have you been including ICH Q8-10/QbD-type information in regulatory submissions for an inhaled or nasal drug product? (Select ONE)

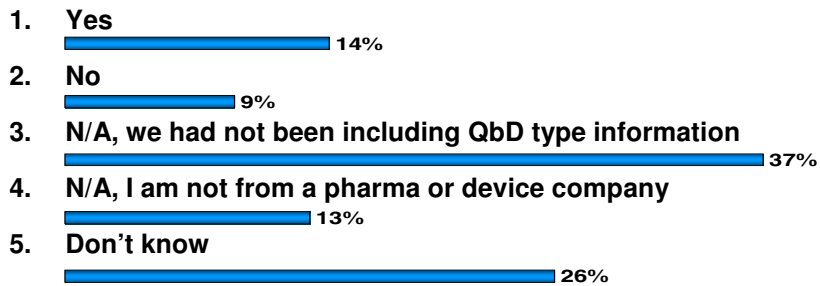


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Q20

If you have included ICH Q8-10/QbD-type information in regulatory drug product submissions pre-2004, did it generally facilitate the regulatory review? (Select ONE)



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Q21

If you have NOT included ICH Q8-10/QbD-type information in regulatory drug product submissions pre-2004, what was the primary reason? (Select ONE)

1. It was not encouraged by FDA or other regulatory agency
 9%
2. Potential complications during review and delay of approval
 11%
3. No clear public guidance as to how to include such information
 5%
4. All of the above equally important
 18%
5. N/A, we had included QbD type information before 2004
 22%
6. N/A, I am not from a pharma or device company
 14%
7. Don't know
 21%

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Q22

If your product includes a device which is not marketed separately as a device, do you go through the SAME development program for the device (e.g., per the EU Essential Requirements) as you would if it were a stand-alone device (e.g., CE-marked)? (Select ONE).

1. Yes
 40%
2. No
 19%
3. N/A, my device(s) is/are marketed separately
 3%
4. N/A, I am not from a pharma or device company
 14%
5. Don't know
 25%

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Thanks for participating in the survey!

After the Case-Study presentation (starting now)
and the Break (3:15-3:45 PM),

WE WILL DISCUSS SURVEY OUTCOMES.

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