

**"Progress Towards Developing an
International Standard for Aerosol Drug Delivery
Devices (ADDD)"**

Hal Yeager, MS, RAC (US)
Eli Lilly and Company
(Chair, ISO/TC84/JWG 5)

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Objectives

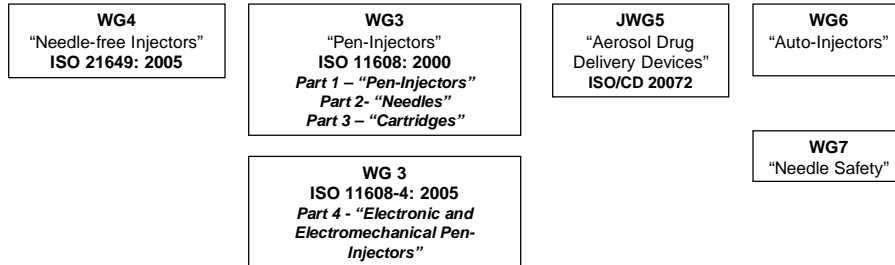
Review of the ADDD Standard

- *Scope*
- *Risk-Based Approach*
- *Participants/Team Members*
- *Status Report*
 - Ø *Overall Timeline*
 - Ø *Document Contents*
 - Ø *Testing Highlights*
- *Key Messages*

“Developing Risk-Based Standards for Aerosol Drug Delivery Devices”

Alignment within ISO TC84

TC84
“Devices for Administration of Medicinal Products and Intravascular Catheters”
 Secretariat: Dansk Standards Association (DS)



“Developing Risk-Based Standards for Aerosol Drug Delivery Devices”

ISO Standards Process (Drug Delivery Systems)

STAGE 0 PWI	STAGE 1 NP	STAGE 2 WD	STAGE 3 CD	STAGE 4 DIS	STAGE 5 FDIS	STAGE 6 ISO
Preliminary Work	New work Item / Draft Docs	Working Draft	Committee Draft	Draft Intl. Standard	Final Draft Intl. Standard	Publication



Needle Safety (WG6) ADDD (JWG5) Pens/Carts (WG3)
 Auto-injectors (WG7) EM Pens (WG3)
 Needle-free (WG4)

In Scope

This international standard applies to performance and testing requirements for hand-held single-use and multiple-use aerosol drug delivery devices (ADDD) intended to deliver metered or pre-metered aerosolized medicinal product to or by means of the human respiratory system.

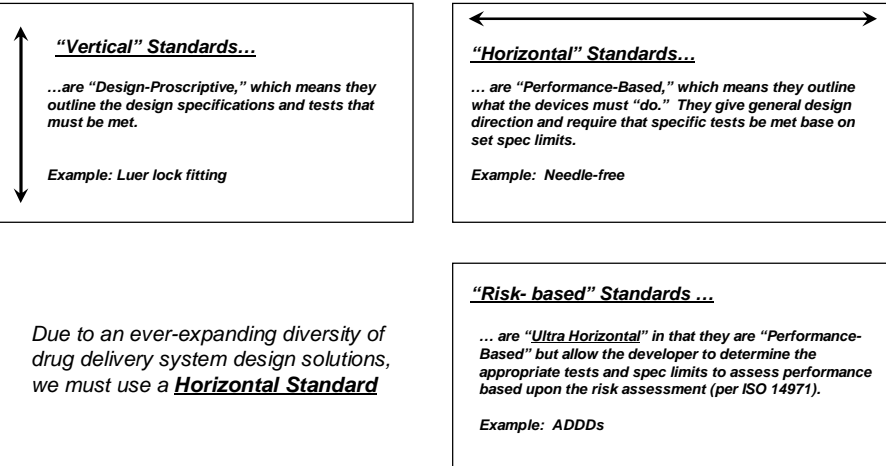
The objective of the standard is to verify that the design of the ADDD consistently meets the manufacturer’s device requirements and performance profile for delivery to or by means of the respiratory tract as determined by a risk assessment

Out of Scope

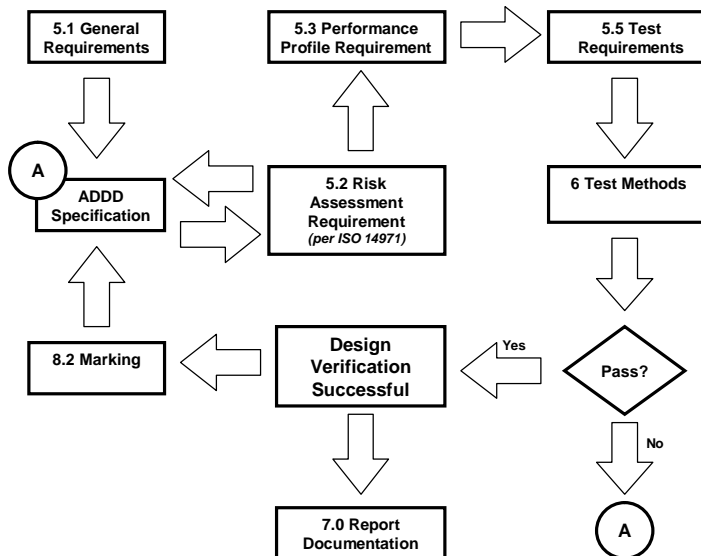
Continuous or semi-continuous aerosolization devices covered in EN 13544-1, aerosolization devices which do not emit API, general purpose aerosolization devices (for use with ventilators, nebulizers and atomizers).

“Developing Risk-Based Standards for Aerosol Drug Delivery Devices”

Goal: Do Not Restrict Innovation



“Developing Risk-Based Standards for Aerosol Drug Delivery Devices”



“Developing Risk-Based Standards for Aerosol Drug Delivery Devices”

Participants/Team members in JWG5

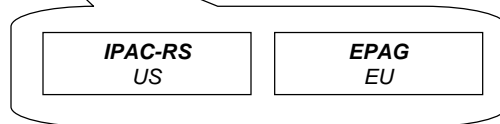
Industry Organizations	Related Device firms	Pharmaceutical Firms	Standard Organizations	Regulatory & Public Health Agencies
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**The strength of the JWG 5
is the breadth and diversity of its members...**

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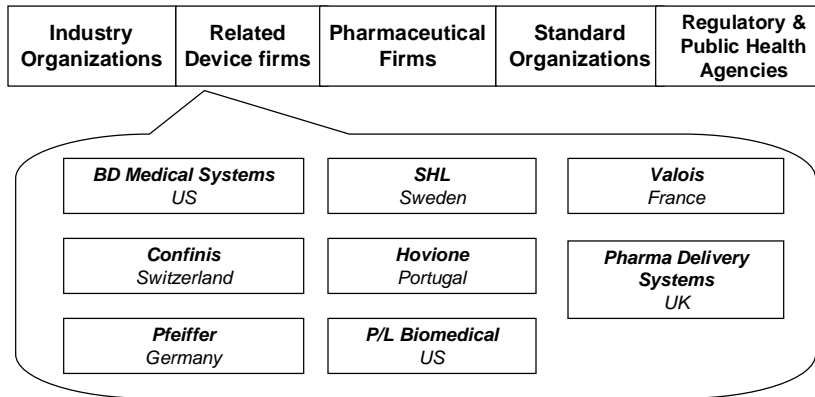
Participants/Team members in JWG5

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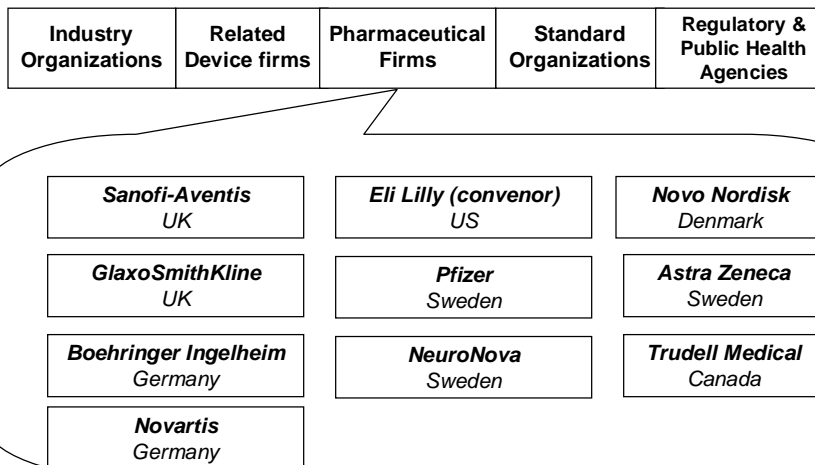
“Developing Risk-Based Standards for Aerosol Drug Delivery Devices”

Participants/Team members in JWG5



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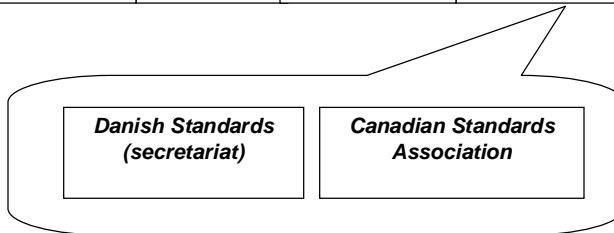
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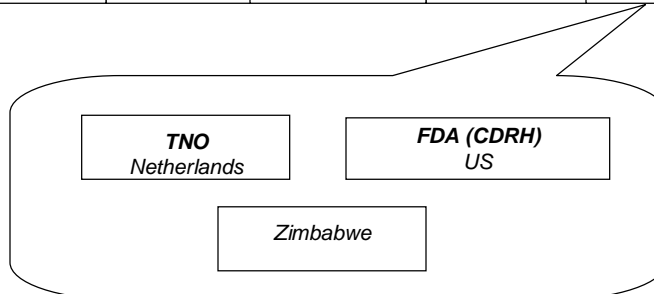
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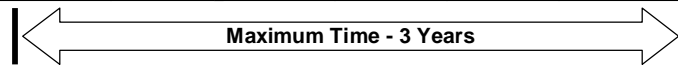
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“Developing Risk-Based Standards for Aerosol Drug Delivery Devices”

Status - Overall ISO Development

STAGE 0 PWI	STAGE 1 NP	STAGE 2 WD	STAGE 3 CD	STAGE 4 DIS	STAGE 5 FDIS	STAGE 6 ISO
Preliminary Work	New work Item / Draft Docs	Working Draft	Committee Draft	Draft Intl. Standard	Final Draft Intl. Standard	Publication



The ISO standards development process requires this to be accomplished within 3 years...

...so, where are we?

“Developing Risk-Based Standards for Aerosol Drug Delivery Devices”

Status - Stages and Meetings

Stage 0	Preliminary Work Item stage
Meetings 1 - 6	Dec 01 – Feb 04 EU/US locations
Meeting 7	Aug 04 Lisbon, Portugal
	15 Jan 04 VOTE: Approval of New Work Item (Stage 1)
Stage 1	New Work Item (proposal stage)
Stage 2	Preparatory Stage (Working Draft stage)
Meeting 8	Jan 05 Washington, DC
Meeting 9	Sept 05 Bern, Switzerland
	Nov 05 ISO/CD 20072 out for Int. Review
Stage 3	Committee (Committee Draft stage)
	Jan 06 ISO/CD 20072 vote for approval as CD
Meeting 10	March 06 Copenhagen, Denmark
	Aug 06 ISO/CD 20072 (v2) out for Int. Review
Meeting 11	February 07 Washington, DC
Stage 4	Committee (Draft Int'l Std stage)
Stage 5	Committee (Final Draft Int'l Std stage)
Stage 6	Publication (Final Draft Int'l Std stage)



“Developing Risk-Based Standards for Aerosol Drug Delivery Devices”

Status - Contents

<u>DRAFT: Table of Contents</u>	-1-
1. Scope	
2. Normative References	
3. Terms and Definitions	
4. Symbols and Abbreviated Terms	
5. Requirements:	
• General Requirements	
• Risk Analysis Requirement	
• Performance Profile Requirement	
• Test Requirements	
6. Test Methods	
	7. Test Report
	8. Information supplied by Manufacturer
	• General
	• Marking
	• Instructions for Use
	Informative Annexes
	Bibliography

Ref N49: Sept 2003

“Developing Risk-Based Standards for Aerosol Drug Delivery Devices”

Testing Highlights

- *Environmental and Mechanical Testing*
 - *Environmental*
 - *In-use conditions testing of the system at temperature*
 - *Storage conditions*
 - *Sterilization and cleaning*
 - *Electro-Mechanical*
 - *Free-fall*
 - *Vibration and Shock*
 - *EMC*
- *Evaluation per the Performance Profile and Risk Analysis*
- *Statistical Methods*
 - *Normal tolerance sampling*
 - *Minimum probability content and confidence (95/95)*

“Developing Risk-Based Standards for Aerosol Drug Delivery Devices”

Key Messages

- **Scope**
 - Evaluation of the device as part of the “System”
 - System and user perspective, not drug/CMC perspective
 - Performance profile defined by risk assessment
 - Avoid conflict with other technical committees (e.g. TC 121, TC 76)
- **Terminology**
 - Due to the various formats for ADDD technology, there are a wide variety of potential manifestations of this art. So, we must be careful not to be too specific (and therefore “limiting”) in our terminology
 - Balance between sufficient detail and being so specific as to restrict innovation

“Developing Risk-Based Standards for Aerosol Drug Delivery Devices”

Key Messages

- Development of the ADDD standard is well represented across a broad range of interests and expertise
- The state-of-the-art is being advanced across a range of technologies (e.g. powder vs. liquid, passive vs. active)
- Standardization requires a Horizontal/Risk-Based approach
- Benefits:
 - Global guidance regarding ADDD system design verification
 - Potential bridging strategy
 - Ø Rigorous design control methodology
 - Ø Compliance with performance profile
 - Controlled “decoupling” of device development from clinical development
 - Ø Milestones and decision points are different for drugs and devices
 - Ø Device changes (e.g. user interface, DFU, cosmetic) to be expected downstream
 - Parallel development of device and drug without disturbing “system”