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Association for Accessible Medicines

Biosimilars Council
A Division of the Association for Accessible Medicines

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ICH Training Activities Update

September 5, 2018

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Background: Need for a Strategy

- EWGs post slide decks at Step 4 – is that “training”?
- Resources (human & fiscal) for ICH-sponsored programs (ex. Q8, 9, 10 and Q3D)
- Increase number & scope of requests for ICH training
- Concern about ad hoc program content
- Needs assessment – unknown
  - –Regulators vs. Industry
  - –Developed vs. Developing countries
  - –Members vs. non-members
- No concerted ICH training efforts or resources allocated at the time
- Opening ICH Membership & GL Implementation requirements

=> ICH Training SubComm formed in 2016

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Developed a Needs Assessment Survey

Questions asked of ICH Members & Observers:

- What priority would you give the GL in terms of training needs
- Should training be directed at regulators, industry or both
- Are you aware of any implementation issues
- Would you consider the content of the GL
  - –to be difficult to grasp/understand;
  - –may cause a significant change in current practice
  - –&/or presents novel ideas or new strategic concepts

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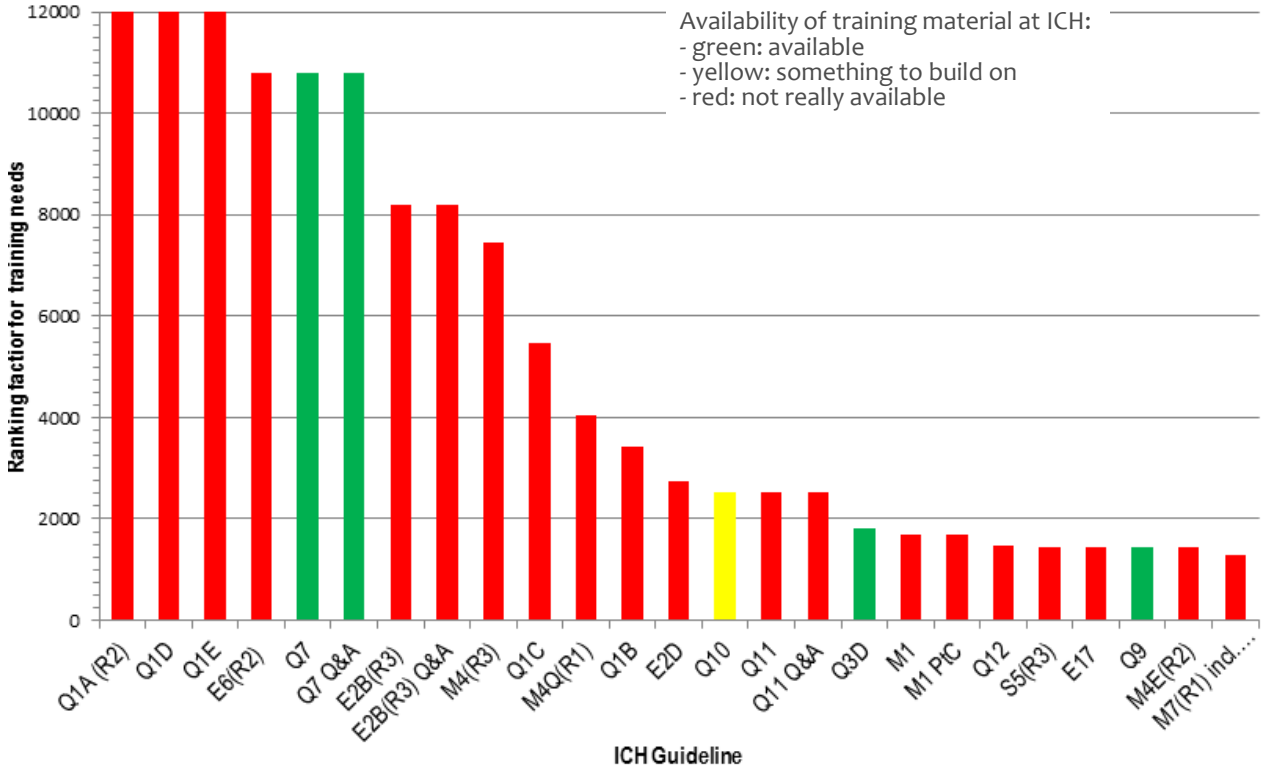
Overall Survey Results

Top Guidelines of Training Needs-ICH Members &Observers)



Combined Survey Results: Summary

- –Basic training material is needed/desired for almost every ICH guideline
- –Implementation issues cited mainly outside EU/Japan/US
- –Training is needed/desired by both industry and regulators

Priority Training Needs:

1.	Q1 Series	Stability testing (incl. Q1F)
2.	E6(R2)	Good Clinical Practice
3.	Q7	GMP for APIs – incl. Q&A
4.	E2B(R3)	Clinical Safety Data Management – incl Q&A
5.	M4(R3)	Organization of the Common Technical Document
6.	M4Q(R1)	CTD Quality - QOS
7.	E2D	Post-Approval Safety Data Management
8.	Q11	Development and Manufacturing of Drug Substance – incl. Q&A
9.	Q10	Pharmaceutical Quality System
10.	Q3D	Elemental Impurities
11.	M1	Medical Directory for Regulatory Activities (MedDRA) – incl.PtC

ICH Training Strategy: Considerations for the MC

- Demonstrated need for ICH training
- Considered an important issue to MC Parties
- Uncomplicated approaches are the best strategy
- Do not duplicate efforts
- Desire high-quality programs - current content
- Resource implications (human and financial) are a concern….

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ICH Training Strategy Proposal: Endorsed by MC

Based upon those considerations, ICH cannot be solely responsible for training (development, delivery, maintenance)

⇒**Working with trusted training providers as a 12 month Pilot**

⇒Training SubComm becomes a Standing Committee to act as facilitator and advisor to support efforts

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ICH 2017 Training Pilot Terms of Reference:

- Roles and Responsibilities of the Training Provider
- Role of ICH and the Training SC
- Funding Issues
- Analysis/Assessment

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ICH

Recognised Training Programme

2017 ICH Training Partner Pilot Programs

Duke-NUS CoRE: ICH Q Topics/CMC Workshop
Northeastern University: ICH Q1 Stability Training
Harvard MRCT Center B&W: ICH GCP Training - E6(R2)
DIA: Short Course on Quality Systems
DIA: Short Course on ICH Safety & Efficacy
RAPS: Intermediate Course-Submissions in eCTD format
PDA: ICH Q7 - GMPs for APIs
(**AHC**: E2 Series Online Training Program)

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2017 Pilot Program Outcomes

- Pilot deemed successful
- Continue to work with Training Partners
- Focus on developing online training materials
- Priority Guidelines = Tier 1 & Tier 2

Q1 (Stability)
Q7 (GMPs for APIs)
E6 (GCPs)

M1 (MedDRA)
M4 (CTD)
E2 (PV)

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Goal: Develop at least one introductory (2018) and one in-depth (2019-2021) online training for Tier 1 & 2 Guidelines (except MedDRA) in English by 2021

Collaborate with Training Partners:

Q1	NEU
Q7	PDA/PICs
E6	Harvard MRCT
E2	AHC
M4	RAPS

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Developing Introductory ICH Online Training Materials: General Guidance for ICH Training Partners

- Outline provided for preparing an introductory overview of an ICH guideline.
- No requirement on format – only that the elements in the outline are addressed. There is no requirement on length.
- ICH Training Partner will own the training program content. The program will be housed on the Partner's website with a link from the ICH website.
- The training should target a wide audience that may have differing knowledge levels of the subject matter.
- Viewing of the training program must be made available free of charge.
- The program should be in English.
- Use of the "ICH Recognized Training Programme" logo may be authorized
- The ICH Training Subcommittee reserves the right to review the materials before posting.

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Goal: Support Priority EWG/IWGs in Developing Training Materials in 2018

E9 EWG

–Deliverable: 3-Module Online Program consisting of introductory animated video; 6 comprehensive moderated slides decks; case studies module

Q11 Q&A IWG

–Deliverable: Online in-depth training module - voice over narration with slides; and 2 case studies

E17 IWG

–Exact deliverable to be determined soon by IWG

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Templates for New Draft and Final ICH Guidelines

TrSC has drafted templates for ICH WGs:

1. Development of standardized informational materials after **Step 2** (while comment periods are open)
Engage in stakeholder outreach (for information and to solicit comments)
Beneficial to have a “harmonized” slide deck at Step 2 that can be used in presentations
Quote directly from the Step 2 guideline – not open to interpretation

2. Developing online slide presentations after **Step 4**

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Goal: Develop a Gap Analysis for Priority Tier 3 Guidelines Trainings

- Determine if any online training programs exist in order to discuss strategy on future activities
- Issue: Define what are the “Priority” Tier 3 Guidelines
- ICH MC input requested and will discuss potential list

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2018 ICH Training Programs

Q1 Stability Training, Brasilia, Brazil, August 7-8

Q1 Stability Training, Boston, MA, USA, October 10-12

See ICH website => Training

www.ich.org

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THANK YOU

Michelle Limoli, PharmD
US FDA
CBER

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