Outline - new regulations, guidance, initiatives and conferences.....

- Background / CASSS CMC EU Forum 2016
- New Medical Device Regulation amending medicines legislation
- EMA perspective
- Human Factors
- ICH Q8, Q9, Q10 vs ISO standards
- ISO 20069 Device change management drug delivery devices
- Current EU initiatives
- International Harmonisation/convergence
  - ... increased interest in the topic!
Drug-device combination products
Increasing complexity of device components

Credit: Mark Chipperfield, CorvusDevice Ltd, MedTech & Pharma Platform 2014
CASSS EU Forum, May 2016, Paris

Regulatory Challenges of Drug Device Combination Products in the EU

Janine Jamieson, MHRA, UK May 2016
Regulation of medical devices

Medical Devices industry
• 25 000 companies, 95% are Small and Medium-sized Enterprises (SMEs).

CE mark: Single market provision
Controls proportional to risk
Class I, IIa, IIb and III

Co-regulation Device CAs and Notified Bodies

*Internal Market, Industry, Entrepreneurship and SMEs
** Public Health and Food Safety

Medical devices: DG GROWTH*
Medicinal products: DG SANTE**
Medical device co-regulation

Role of Competent Authority

- Initial Designation of notified bodies and ongoing surveillance
- Pre Market Clinical Investigation
- Post Market vigilance
- Enforcement

- Currently 28 Member states until March 2019

Role of Notified Body

- Independent test and/or certification bodies
- Conformity assessment procedures for specific range(s) of products
- Level of involvement dependent on risk classification of medical device

- Currently approx. 55 (from 80 following stringent dual audit)
EU Guidance - now under revision

EUROPEAN COMMISSION
DG ENTERPRISE and INDUSTRY
Directorate F, Unit F3 “Cosmetics and medical devices”

MEDICAL DEVICES: Guidance document

Borderline products, drug-delivery products and medical devices incorporating, as an integral part, an ancillary medicinal substance or an ancillary human blood derivative

GUIDELINES RELATING TO THE APPLICATION OF:

MEDDEV 2.1/3 rev 3

Foreword

The present Guideline is part of a set of Guidelines relating to questions of application of EC Directives on medical devices. This guideline is not legally binding, since only the European Court of Justice can give an authoritative interpretation of Community law. It has been elaborated by an expert group including experts from Member States’ Competent Authorities, the Commission’s services, as well as industry trade associations. It is therefore intended that the document will provide useful guidance which should assist common positions to be taken throughout the European Union. Due to the participation of the aforementioned interested parties and of experts from Competent Authorities, it is anticipated that these guidelines will be followed within the Member States and, therefore, ensure uniform application of relevant Directive provisions.

The present guideline provides non-exhaustive lists of examples of medical devices, accessories to medical devices and medicinal products. Further examples may be found in the manual on borderline and classification in the Community Regulatory framework for medical devices, published on the European Commission website. Particular attention should be paid to borderline cases between medical devices and herbal medicinal products. This issue may be further developed in this guidance in the near future.

Note: This document is a revision of an earlier document published in July 2001 as MEDDEV 2.1/3 rev 2. Some of the examples given in the MEDDEV 2.1/3 rev 2 have not been included in the present Guideline. These examples will be further elaborated in the above mentioned manual on borderline and classification in the Community Regulatory framework for medical devices.

This guidance incorporates the changes introduced by the Directive 2007/47/EC. These changes have to be applied as of 21 March 2010.

2 OJ L 247, 21.09.2007
Regulation of Combination Products

Case Study: Faslodex

Syringe containing pharmaceutical formulation

Needle supplied with the syringe and attached prior to administration

Combination Product Type

- Single entity / integral, not reusable, pre-filled syringe co-packaged with safety needle

Primary Mode of Action

- PRE-FILLED SYRINGE AND NEEDLE CONSTITUENT
  - DRUG

Lead Regulatory Agency

- DRUG (CDER)
- DRUG (NDA)

Regulatory Approval Process

- PRE-FILLED SYRINGE CONSTITUENT
  - DRUG
  - DEVICE

- NEEDLE CONSTITUENT
  - DEVICE

Same product → Different regulatory designation and approval pathway
Medicines with integral device component

Regulated under 2001/83/EC BUT

- device component needs to be considered by medicines CA.
Whereas .......

**Medical devices incorporating ancillary medicinal substances**

*Medical Device Directive 93/42/EC:*

The quality, safety and usefulness of the substance must be verified by analogy with Annex I to Directive 2001/83/EC.

- Class III high risk devices under rule 13 of MDD
- Notified Bodies consult Medicines CA or EMA for opinion on medicinal substance
What has happened since then?

A lot!!!!!
DIA Combination Products conference, 24-25 Oct 2017
New Medical Device and IVDR regulations

Revision to EU Medical Device Legislation

Medical Device Directive 93/42/EC
Active Implantable Device Directive 90/385/EC
In Vitro Diagnostic Device Directive 98/79/EC

Medical Device Regulation EU 2017/745
In Vitro Diagnostic Device Regulation EU 2017/746

3 year transition May 2020
5 year transition May 2022

Link: https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en
Medicines-Device Borderline and Classification

- **The importance of classification**
  - In Europe two sets of legislation and regulatory systems that operate differently
  - A product is EITHER a medicine (medicinal product) OR a device
  - Combinations of medicines and devices are common but there is no ‘combination product’ classification

- **Borderline relies on Principle Mode of Action in the claims**

- For combination products the two sets of legislation work together but do not duplicate requirements

- For Medical Devices Competent Authorities co-regulate with Notified Bodies

These principles are not changing
(10) Products which combine a medicinal product or substance and a medical device are regulated either under this Regulation or under Directive 2001/83/EC of the European Parliament and of the Council.

- The two legislative acts should ensure appropriate interaction in terms of consultations during pre-market assessment, and of exchange of information in the context of vigilance activities involving such combination products. For medicinal products that integrate a medical device part, compliance with the general safety and performance requirements laid down in this Regulation for the device part should be adequately assessed in the context of the marketing authorisation for such medicinal products. Directive 2001/83/EC should therefore be amended.
New Article 117 amending MPD

**Article 117 Amendment to Directive 2001/83/EC**

In Annex I to Directive 2001/83/EC, point 12 of Section 3.2. is replaced by the following:

'(12) Where, [the product is governed by the MPD] … the marketing authorisation dossier shall include, where available, the results of the assessment of the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation contained in the manufacturer’s EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device.

If the dossier does not include the results of the conformity assessment referred to in the first subparagraph and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017…+, the authority shall require the applicant to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation issued by a notified body designated in accordance with that Regulation for the type of device in question.
HMA & CAMD Borderline and Combination Products Working Group

Advise HMA & CAMD on issues relating to the MP/MD borderline and regulation of so-called “combination products”

- To reach common understandings between Member States in relation to interpretation of legislation relevant to the borderline. To provide a forum to discuss the classification of products to aid in decision-making
- To agree common understandings and best practices around assessment and regulation of so-called “combination products”
- To identify gaps in legislation relevant to these products and propose guidance to ensure consistent regulatory decision making and protection of public health,
- (achieved by working through established European networks where possible)

(Excerpts from mandate agreed October 2016)
EMA increasing mention of medical devices

**Concept papers:**
- developing a guideline on Quality requirements of *medicinal products containing a device component* for delivery or use of the medicinal product, (Feb 2017)
- revising of the guideline on the pharmaceutical quality of *inhalation and nasal products* (Mar 2017)
- predictive biomarker-based assay development in the context of drug development and lifecycle (development of *companion diagnostics for precision medicines*) (Aug 2017).

**Q & A guidance:**
- Marketing Authorization Pre-authorization guidance Quality Section 3.3.11 Medical Devices (Aug 2017)
- Scientific guidelines Q&A on Quality Part 2 Specific types of product - Needle safety systems (Sep 2017)
EMA perspective on increasing focus on review of device components of medicinal products

TOPRA Annual Human Medicines Symposium
2–4 October 2017 - Victoria Park Plaza Hotel, London

Presented by Armin Ritzhaupt, PhD on 04 October 2017
EMA, Regulatory Affairs Office, Scientific and Regulatory Management Department
EMA’s current role in review of medicinal product and medical device combinations

Medicinal products and drug delivery medical devices
- Non-integral (CE-mark required prior to CHMP opinion)
- Integral (No CE mark required)

ATMP combination products
- One or more medical devices as an integral part of the medicine
- Existing procedural advice on the consultation of Notified Bodies

Medicinal substances incorporated in medical devices (ancillary)
- Consultation of NB with NCA/EMA
- Established procedure and guidance for initial and post-consultation (210 days)
Medicinal product-medical device combinations - what is **within** EMA remit? (3/3)

- **For all devices in combination products**
  - Authorising product information to ensure safe and effective use (can include instructions for use in the package leaflet)
  - Requesting risk minimisation measures (e.g. training for complex devices)
  - Post-market surveillance
  - Device failure, dosing errors, decreased efficacy resulting from difficulty to use the device, etc...

**PRAC Good practice guide on risk minimisation and prevention of medication errors**


- Authorising changes of device component during product lifecycle
EMA support for combination products

- **Regulatory and Scientific Advice**
  - Available from EMA or National Competent Authorities
  - Can be used at any stage of development – earlier the better!

- **EMA Innovation Task Force (ITF)**
  - Facilitate understanding of issues and regulatory requirements to bring innovative products and processes to market:
    - ATMPs, stratified medicines, nanomedicines, advanced manufacturing techniques, novel drug/device combinations. Applicable to medicines and devices.

- **ATMP classification procedures for combined ATMP**
  - Regulation 1394/2007/EC
    - Incorporates as an integral part of the product one or more (active implantable) medical devices; cellular or tissue part is viable; in case of non-viable cells or tissues, the action must be primary to that of the device(s)
    - CAT may require consultation of a Notified Body on the conformity of the device part with Annex I of Medical Device
Examples of identified ‘device’ concerns during review

- **Container closure system**: specification; sterilisation methods
- Compatibility/suitability of drug product with the proposed dosage device
- **Dosing accuracy and precision**
  - Declaration of CE missing / information from NB missing
- **Suitability of the drug delivery system** (e.g. risk to the patient from potential contamination of the vial adapter surface, in-use)
- Comparability study between clinical trial version and commercial product
- Adequate release specifications to identify possible performance failures
- Justification why application devices were not explored as a covariate in the population PK analysis
- Product labelling (readability, use, disposal)
- Risk Management Plan
  - Risk of medication errors (e.g. due to some similarity of devices)
  - Administration of correct dose

EMA perspective on review of device components of medicinal products
Proposal for EMA guideline on quality requirements for drug device combination products (2)

Dossier requirements for integral and non-integral combination products
- Lack of clear guidance for industry or assessors for assessment of medical device component along with medicinal product

Product Information
- Considerations for specific information to be included in the SPC, labelling and leaflet

In EU, no definition in regulation for a medicinal product and medical device presented together (except for ATMPs)

Usability study requirements
- Target patient population with relevant clinical conditions

Product lifecycle management
- Data requirements for variations

EMA perspective on review of device components of medicinal products
Procedural advice on the evaluation of combined advanced therapy medicinal products and the consultation of Notified Bodies in accordance with Article 9 of Regulation (EC) No. 1394/2007

<table>
<thead>
<tr>
<th>Discussion at CAT</th>
<th>July 2009</th>
</tr>
</thead>
</table>
| Discussion at EMA/CAT-NB Coordination Group | 23rd March 2010  
21st April 2010  
2nd June 2010 |
| Presented to CAT for 1 month consultation | June 2010 |
| Adoption by CAT for release for external consultation | 16th July 2010 |
| End of consultation (deadline for comments) | 29th October 2010 |
| Discussion at EMA/CAT-NB Collaboration Group | 24 November 2010 |
| Presented to CAT for 1 month consultation | January 2011 |
| Adopted by CAT as final version | 11 February 2011 |
Concept paper comments - summary

Concept paper consultation

Individual pharmaceutical companies
Industry associations (pharma and medical device)
Individuals
Notified Bodies
Primarily EU; but also Canada, USA

General comments

Proposal to develop guidance is welcome; needed across EU
Alignment with new MDR (Art 117)
Engagement with device stakeholders positive; appreciate WS/training; address advice for development
Consistent wording/terminology (ISO), more clarity on scope (applicability for clinical trials?); global alignment
EMA Fellowship Combination products

- **Fellowships**
  - Aim: advance scientific and regulatory understanding, usually a 2-week exchange
  - 22 EMA fellowships at FDA in the last 4 years
  - 5 more this year – 2 currently in progress (MRA, Combination products)

- **Past years:**
  - GMP inspections (x2)
  - Risk communication
  - Raw data analysis (x2)
  - Pharmacovigilance
  - Qualification of clinical outcome measures
  - ISO standardisation
  - Patient engagement
  - Veterinary medicines (x3)
  - Legal aspects
  - IVIVC
  - Accelerated access to medicines
  - Rheumatology and gastroenterology
  - Quality of medicines
  - Transparency
  - Communications
  - Real world data and big data
  - Orphan medicines
  - Paediatric medicines

**Credit:** Sabine Haubenreisser, EMA liaison officer at FDA
Notified Body perspective

TOPRA Annual Medical Devices Symposium 2017

Article 117
A Notified Body perspective, advice on how and when to engage notified bodies

Theresa Jeary, Head of Notified Body Medical Devices, LRQA
NB Assessment Report?

- The product approval is ultimately determined by the Medicines Agency who shall take into consideration all the evidence provided.
- Important that the NB assessment report provides sufficient details to the Medicines Agency of what the NB has assessed and details the conclusion re suitability of conformance to Annex I to enable an informed assessment.

Important for NBs to engage with Medicines Agencies to understand their perspective to facilitate the process.

Credit: Theresa Jeary LRQA
Documentation Expectations for a Drug Delivery Device

- Scientific data to demonstrate conformance to the General Safety and Performance Requirements detailed in Annex I of the MDR
- Common sense requirements relating to safety and performance of the device
- Split into
  - General Requirements &
  - Requirements regarding Design and Manufacture
Human factors

The Device Side of Combination Products
Technical and Regulatory Challenges in Life Cycle Management

Bob Laughner
Associate Director, Combination Products

04 May 2016
Why Make Changes During LCM?

• Improve Performance, Safety, and/or Usability
• Improving Manufacturability or Production Yields
• Addition of New Features or Functionality
• Supplier Changes
• Improvement or Discontinuation of Materials or Components
• Complaints/CAPA

Credit: Bob Laughner, MedImmune
Challenges in Determining Change Submission

- FDA Draft Guidance – “Submissions for Postapproval Modifications to a Combination Product Approved Under a BLA, NDA, or PMA”

<table>
<thead>
<tr>
<th>Type of NDA/BLA Submission for a Change in a Device Constituent Part of a Combination Product Approved under an NDA/BLA</th>
<th>Then Submit Information on the Device Change Using This Type of NDA/BLA Submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>If the Device Constituent Part Were a Stand-Alone Device Approved under a PMA and the Change Would Have Required the Following Submission</td>
<td></td>
</tr>
<tr>
<td>PMA Original</td>
<td>NDA/BLA Original</td>
</tr>
<tr>
<td>PMA Panel-Track Supplement (New indication/population, without any other change to the constituent parts, supported by new clinical data and the original preclinical data)</td>
<td>Prior Approval Supplement (Efficacy)</td>
</tr>
<tr>
<td>PMA 180-day Supplement (Design change and labeling change supported by new preclinical and/or limited confirmatory clinical data)</td>
<td>Prior Approval Supplement (Efficacy)</td>
</tr>
<tr>
<td>• Design</td>
<td>Prior Approval Supplement (Efficacy)</td>
</tr>
<tr>
<td>• Manufacturing site change</td>
<td>Prior Approval Supplement (Efficacy)</td>
</tr>
<tr>
<td>• Labeling change including nomenclature (And with a change from the next column)</td>
<td>Prior Approval Supplement (Labeling)</td>
</tr>
<tr>
<td>Significant labeling change that does not qualify for a Special PMA Supplement - Changes Being Effect, does not change the indication, and does not include a design change</td>
<td>Prior Approval Supplement (Manufacturing or Labeling)</td>
</tr>
<tr>
<td>PMA Real-Time Supplement (Design or labeling change that does not require clinical data and for which the data provided fall within only one scientific discipline, e.g., electrical engineering, microbiology, or sterilization)</td>
<td>Prior Approval Supplement (Manufacturing or Labeling)</td>
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<tr>
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<td>Prior Approval Supplement (Manufacturing or Labeling)</td>
</tr>
</tbody>
</table>

Credit: Bob Laughner, MedImmune
ISO Change Management Standard

Change assessment of devices intended for administration of medicinal products

Paul Jansen, PE
Board Member & Senior Advisor
Haselmeier

3rd June 2017
Scope & Proposal

Credit: Paul Jansen, Haselmeier
Aim & Challenges

Change Management means:
Analyze and test for impact to

- Safety
- Efficacy/Effectiveness
- Performance

According to standard practices:

- 21 CFR Part 820
  - 820.30 Design Controls
- ISO 13485
  - Control of design and development changes
- Software Validation Guidelines

Challenges

- To be clear and concise
- To be global and get more regulatory inputs
- To be descriptive not prescriptive
- To achieve consensus of the committee
Regulatory perspectives on CQAs, CPPs, and Risk Analyses for Combination Products.

3rd FDA/PQRI Conference on Advancing Product Quality
March 22-24, 2017
TRACK #2 Achieving Drug Product Quality: Novel Approaches and Applications
Session 5. Drug/Device combination products: Quality

Douglass Mead, Senior Director, Regulatory Affairs CMC,
Medical Devices and Combination Products

Janssen Research & Development, LLC

Also:
• Clint Judd, Amgen, on Shelf-life considerations
• Irene Chan, FDA, on Human Factors for ANDAs
Combination product risk assessment and control strategies combine Q9 and ISO 14971 approaches with added focus on drug risks to patients.

Where does the combination product risk (severity) fit? You must decide.

- mAb autoinjector for RA/PsO
- insulin pen -injector
- Epinephrine autoinjector
- OTC Allergy nasal sprays
- Triptan nasal sprays
- Controlled drug nasal sprays
- Scopolamine patch
- Contraceptive patch
- Analgesic patch
- Asthma inhalers (long term)
- Asthma inhalers (acute/rescue)
- Syringe/needle kits ???

Increasing risk of harm

Criticality (Accuracy / Reliability / Quality / Potency / Performance / Usability / Labeling) Requirements

- Objective: The team’s deliberation, risk prioritization (severity & probability for each hazard), and mitigations implemented matter most.
- Goal: Determine a level of acceptable “residual risk”
Aligning device and drug development

Mapped General Concepts for Development

Device constituent part development


Intended function >>> Essential Performance

Design Controls

Risk analysis – ISO 14971

Design V&V

Shelf Life

IND Development Pathway

Part 4 cGMPs

CQAs

CMAs

Lot release tests

Process Development & Validation

Human factors studies (DMEPA)

CPPs

qTPP

ICH Q8, Q9, Q10

BLA/NDA

Drug-device Combination product development

Functional Stability
Combination product developments at FDA

- Combination products related developments in brief
- Combination Products Council
- Section 3038 of 21st Century Cures
- Final rule on postmarketing safety reporting
- Final guidance on CGMPs
- Final guidance on classification of products as drugs or devices and associated considerations
- Finalizing guidance on human factors
- Intercenter consult process pilot
- Finalizing Pre-RFD guidance
- Finalizing guidance on postmarket changes
- User fee commitments
  - Drug/biologic-led combination products
  - Complex generics
- Center-led initiatives
  - Generics
  - Medical apps
Combination Products Council

- Senior-level internal forum to address combination product issues raised by its members
- Chaired by the Deputy Commissioner for Medical Products and Tobacco or his/her designee, and includes the Center Directors for CBER, CDER, and CDRH and the Office Director for OCP, or their designees

21st Century Cures Act

- Product classification and assignment
- Premarket Review
- Postmarket Regulation
- Other
Key messages for future regulation

General observations/take-aways

• Focus on efficiency, consistency and coordination
• Commitment to a risk-based approach
• Commitment to speaking with one voice
• Desire to hear from you and work together
• Looking to OCP as a resource
European Initiatives (1)

Key issues

- Both sectors have and will experience continued change over the coming years.
- Heightened public awareness and expectation around health product safety and performance issues. Build/rebuild TRUST.
- Health products are also becoming increasingly interdependent as technologies converge.
- Existing paradigms are challenged not only by converging technologies but the emergence of new technology areas.
- New borderline issues and clarity is required around regulatory roles and pathways for combination products (including companion diagnostics).

Specific challenges

- Borderline products
- Substance based devices (new MDR)
- Combination products
- Tissues & cells/blood incl ATMP
- Near-patient manufacturing
- Companion diagnostics/biomarkers
- Vigilance/pharmcovigilance
- Clinical research
- Global harmonization initiatives
- Supply chain integrity
- Software/apps/ artificial intelligence
- Wearable/connected health/closed loop
- Horizon scanning for new technologies

MDR: Medical Device Regulation
European Initiatives (2)
Industry collaboration

EBE paper: Industry Perspective on the marketing application technical requirements and regulatory review for medicinal product containing a drug delivery device component

Serge Mathonet Sanofi R&D Global Regulatory CMC Biologics

EU CMC STRATEGY FORUM MAY 22-24, 2017 IRELAND
Harmonization Efforts - DIA Combination Products 2017

Title: Guidance on Regulatory Practices for Combination Products

Authoring Group: Work Group 1, Pre-Market: General MD

Date: 26 November 2016

ICH Q12 Combination products
What is the CPC?
A group of leading companies in the drug, device and biologics industries, the CPC works to improve the regulatory environment for combination products by developing and advocating policy positions on regulatory issues affecting combination products.

What is the CPC’s mission?
The Coalition’s Mission is to improve the regulatory environment for combination products. To that end, the Coalition focuses on developing and advocating policy positions on issues affecting combination products.

Credit: Tim Chesworth, AZ
Recent events (1)

- Workshop exercise – Critical Thinking and Risk Management
- Auto-injector used for life-threatening emergency treatment
- FDA Warning letter, Sept 2017
Recent events (2)

## 2017 PDA Europe Conference, Exhibition

**The Universe of Pre-filled Syringes & Injection Devices**

**Improving Patient Outcomes with Innovative Drug Delivery**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7-8 Nov 2017</td>
<td>Austria Center Vienna, Austria</td>
<td></td>
</tr>
</tbody>
</table>

### Closing Plenary

**Moderator:** Georg Roestling, PDA Europe

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>13:45</td>
<td>Manufacturing Highlights: Syringe Filling, Device Manufacturing</td>
<td>Jerry Cacia, Roche</td>
</tr>
<tr>
<td>14:15</td>
<td>Evolution of UPFS - From Little Beginnings to a Vastly Extended Universe</td>
<td>Mathias Romacker, Pfizer, Hanns-Christian Mahler, LONZA</td>
</tr>
<tr>
<td>14:30</td>
<td>Coffee Break, Poster Session &amp; Exhibition - Featuring live Demo Booths</td>
<td></td>
</tr>
<tr>
<td>15:00</td>
<td>The Future of Parenteral Drug Delivery in a Connected Health Ecosystem</td>
<td>Divakar Ramakrishnan, Eli Lilly</td>
</tr>
<tr>
<td>15:30</td>
<td>Closing Panel Discussion: Improving Patient Outcomes with Innovative Drug Delivery - Expectations for the Future</td>
<td>Manfred Maeder, Novartis, Laurent Jeannin, GSK</td>
</tr>
<tr>
<td>16:30</td>
<td>Closing Remarks &amp; End of the Conference</td>
<td>Georg Roussling, PDA Europe</td>
</tr>
</tbody>
</table>
Summary

- The new EU Medical Device Regulation amends medicines legislation requiring notified body review of integral delivery devices
- Questions about how this will work, extent of review?
- EMA perspective - now issuing guidance on medical device components
- Increasing recognition of human factors for safe and effective use of combination products
- Life cycle management for drug delivery devices considering both pharma and device perspectives
- Current EU and international initiatives
- Cooperation between regulators as well as industry groups
Acknowledgements

- Mark Chipperfield, Corvus Device
- Tim Chesworth, AstraZeneca
- Elizabeth Baker, John Wilkinson and Ian Hudson, MHRA
- Armin Ritzhaupt, Sabine Haubenreisser, EMA
- Theresa Jeary, LRQA
- John (Barr) Weiner, FDA
- Bob Laughner, MedImmune
- Paul Jansen, Haselmeier
- Doug Mead, Janssen
- Serge Mathonet, Sanofi, EBE

THANK YOU!