PDA Interest Group: Combination Products

Meeting details

The inaugural meeting of the Combination Product Interest Group was held prior to 2013 PDA Europe: The Universe of Pre-filled Syringes and Injection Devices; on 4th November 2013, in Congress Center, Basel, Switzerland.

Background

There are two Interest Groups proposed:

- PDA Interest Group: Combination Products, EU
    - Lead: Mark Chipperfield
    - Head of Device Development, F. Hoffmann-La Roche, Basel, Switzerland
- PDA Interest Group: Combination Products, US
    - Lead: Lee Leichter
    - President, P/L Biomedical, US

For the initial meeting, both groups were combined.

Attendance

The inaugural meeting was well-attended by Medical Device companies, Pharma companies, Suppliers and Consultants to the industry.

- Attendee list is available here: ……..

Members participating ranged from those new to this product area, through to those who have extensive experience with combination product development, industrialization and commercialization.

It was suggested that additional participants might be sought, depending upon subject matter and future discussion topics – these might be 'guests' or additional 'members'. It was pointed out the membership in an IG is allowed without PDA membership.

Presentations

General material was presented to facilitate discussion of scope, purpose, future intentions.

- Slide deck can be found here: ……

Purpose

The leads proposed that the overall purpose of the Interest Groups be;

'To provide a forum for topical issues concerning technical, regulatory (submissions) and compliance matters uniquely related to drug delivery combination products with emphasis on delivery devices and functional pharmaceutical packaging.'

This purpose statement was broadly accepted.

It was emphasized that;

- Interest groups are Participatory
- Leaders provide organization and leadership
- Support and help is expected from Members in the following areas;
    - Organizing Meetings and Workshops
    - Website content
    - Webinar Content
    - Any other help offered

Personal aims across the meeting participants were identified. These differed and ranged from wishing to learn about this area, to understand regulation and its application, and to influence future direction of regulators, legislation and industry normative standards;

- To listen
- To share issues and views
- To learn
- To discuss
- To understand regulations
- To contribute
- Understand clinical requirements
- Application of the theory
- Understand "Human Factors"

Scope

Proposals for scope were made by the two meeting Leaders. Initial scope was positioned to try and align with general PDA scope, however the leads and participants see certain benefit in the inclusion of certain technology types that 'stretch' the PDA perspective. After clarifying discussions, the resulting scope is listed below. This can be adjusted at any time in the future, subject to participant wishes and group benefit;

- Reusable and disposable technologies such as;
    - Auto Injectors, Patch Injectors, Pen Injectors/Pumps, Needle-Free Injectors, Infusion Pumps, other large volume infusion/bolus delivery technologies, Skin "Disrupter" Technologies, Manual Assist Devices (e.g. Carpuject/Vaccuject), Catheter Inserters, Micro needle/Transdermal Patchs, Pre-Filled Syringes, Integrated Safety Devices…

- … across mechanical and electro-mechanical engineering solutions
- For the immediate term, implantables will remain out of scope.
- It was generally felt that 'accessories' such as Medical Devices that may be co-packed to form 'convenience' kits, were out of scope for this Working Group and that we should maintain focus on the 'higher' technologies, since this is where regulation application and navigation throws up more significant challenges.
- Participants felt it was useful to also include Training/Demonstration 'Devices' into scope; although these are not regulated generally as Medical Devices or Combination Products.
- In order to set context for the use of the above technologies, the Leaders proposed that we should consider field of use to include 'Hospital', 'Clinic', 'Home'. Additional to this it was suggested that 'Military' and 'Vehicle' environments should also be considered.
- In terms of users, discussion concluded that the following broad user groups should be considered for future work;
    - 'Professional' (Nurse, Doctor, Pharmacist, technician)
    - 'Non-Professional Carrer' (Friend, Spouse, Relative)
    - 'Patient' (Self)
    - 'Bystander' (Emergency)
- Some discussion ensued regarding relevant regulations. It was recognized that most participants consider EU and US regulations as the primary influencers on their strategy, development activities and day-to-day work. However, it was correctly raised that other regions are working intensively on their local requirements and thus should be considered;
    - Additional most significant regulations were considered to be those for Australia, Canada, China, and Japan.

Initial Topics

Some discussion was taken to identify key topics of interest for future discussions, presentations, position papers or influence;

- Share inspection experience between companies
- Roles and responsibilities between device supplier/CMO and the customer/client/recipient
- Design Verification testing
    - Compared to the Respiratory/Inhalation environment, where IPAC-RS have published guidance for 'standard' testing approaches, there is nothing similar for the parenteral space.
- Practical interpretation of HF requirements
    - HF studies vs HF Engineering

    - The use of HF research as Design Inputs
    - Acceptance criteria / Determination of what Design Validation results are 'acceptable'
    - HF vs Clinical testing & requirements
    - HF and Training/Demonstration Devices
- Risk Management
    - How to manage at the product level
    - Performing Risk-Benefit analysis
    - Scientific interpretation of risk
- Determination of requirements for Training/Demonstration devices

These ranged broadly but fundamentally focused in two areas; 'Share Experience' and 'Form a position and influence'.

However the breadth and scope of the topics suggested was very broad. The IG agreed to try to focus the most important (top three) topics on which the activities of the IG should initially focus.

Finally, it was proposed that the IG website feature a library of relevant regulations, directives, legislation and guidance, to act as a working reference resource for members.

Future approach

Several proposals were made regarding approaches to information sharing and topic progression in the future. These ranged across short updates, targeted conferences, meetings at convenient time points leveraging other PDA activity, Case Studies.

Contact to Authorities was favored by the IG, and needs to be considered.

It was agreed to have at least one in-person meeting of the joint IG in conjunction with the annual PDA Universe of PFS.

Actions

- IG Leads to generate minutes of meeting and circulate to all participants, plus raise to website
- IG Leads to list suggested and possible topics and provide to members, by e-mail to attendees/members and on website, asking for each member's prioritization so that the IG would be able to focus on those issues currently most important to the group. These would be used to identify next steps for discussion content, environment & timing.
- IG Leads to initiate construction of website content, including reference library.

Specific Discussion

A specific topic was taken to facilitate some further discussion across the meeting participants. Some key points were raised for consideration…

- Regulators position regarding roles and responsibilities between device supplier/CMO and the customer/client/recipient

- The past model of 'purchase' and use is no longer applicable or likely to meet with Regulator acceptance.
- "Your Company" has responsibility
    - How does this work in practice? ….
        - Supplier selection is required
            - Documented evidence needed for selection and evaluation
        - QA Agreement needed
        - Supplier monitoring is required
        - Product control strategy needs to be implemented
            - Supply and Product Specifications need to be traceable to the development work and to the strategy definition/documentation
        - "Your company" requires the necessary competency to oversee
        - Active participation is expected
        - Submission strategy must be clearly defined at the outset – DMF/MAF/NDA etc
        - Recognize the EU practice is different to the US practice