# REGULATORY AFFAIRS & QUALITY WORKING GROUP

# ACTIVITIES OF THE GROUP PRESENTED AT THE ANNUAL GENERAL ASSEMBLY OF AIPES ON 10 MAY 2017 IN BRUSSELS

Peter Bradley
10 May 2017

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## GROUP OBJECTIVE

**Become a proactive contributor to the European regulatory framework and represent AIPES member views, for regulatory affairs and quality, in consultation with European authorities and associated organisations**

# Group Leader Summary

**In progress:**

- EDQM participation regarding RP monographs of EP
- Organization of symposium Q4 2017 (open to attendance of participants from AIPES member companies extended to EMA/ CMDh)

**To do:**

- Inclusion of Medical Devices to the scope of WG
- Interaction with the other working groups within AIPES =benefits
- Providing inputs from WG members, regarding WG agenda topics and 2017 symposium suggestions etc.
- Providing greater work sharing of topics within RA&Q WG members

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## EXECUTING 3 YEAR PLAN – 2016-2019

- **Further interaction with the CMDh and EMA-**
  - LEU nuclide conversion- support for further applications (work-sharing benefits)
  - Explore other regulations and requirements – possible future interactions, including invitation to proposed 2017 Symposium
- **Involvement with EDQM** an expert group reviewing proposed new, or changes to existing, pharmacopeia monographs
  - Representation from the RA&Q working group now established
- **Review regulatory guidance and directives** to ensure members are informed of changes and submit comments on behalf of members, in order to influence regulatory authorities during consultation procedures
  - Regulatory update table (quarterly update)- What's new
  - Conferences/seminars- proposal to hold seminar on regulatory developments with expert speakers: London Q4 2017
- **Expand use of the AIPES website** to provide access to information for members, to more effectively utilise tools and information- Expert resumes for members seeking advice

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## REPRESENTING OUR MEMBERS- RECENT ACTIONS

- **European LEU nuclide conversion-** support for further applications (work-sharing benefits)
- **PET cassette "kit" proposal from CMDh to EMA-** watching brief and potential lobbying in consultation period for changes
- **Mo-99/Tc-99m generator safety reporting confusion-** EURD list and EMA- clarifying dates and plan
- **FDG manufacture and distribution without approved MA's-** initiating evaluation
- **Barcode and falsified medicines control relating to radiopharmaceuticals-** Clarification of current guidance

# REGULATORY AFFAIRS & QUALITY WORKING GROUP

## THE TEAM

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|---|---|
| Peter Bradley, Chair | GE Healthcare, UK |
| Hatice Erkan, Vice Chair | Monrol Europe, Turkey |
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| Roy Brown | Curium Pharmaceuticals |
| Cristiana Gameiro | IBA, Belgium (+EDQM representative) |
| Shirley Jarvill | Lantheus Medical Imaging, Ireland |
| Ger Mannie | Curium Pharmaceuticals |
| Kai Vetterlein | Eli Lilly |
| Dorothee Philippe | IRE, Belgium |
| Izabela Rejdych | AAA - France |
| Joana Brilhante | AMNI, Belgium |
| Michael Nader | VP AIPES |