



*European Industrial Pharmacists Group*  
*Aggiornamento AFI*

# *What is EIPG?*

*E.I.P.G. is a European association representing the national, professional organizations of pharmacists employed in the pharmaceutical or allied industries of the Member States of the European Union, the European Economic Area, or European countries having a mutual recognition agreement with the European Union on compliance control of regulated medicines.*

# The Faces behind EIPG



Claude Farrugia  
*President*



Jane Nicholson  
*Executive Director &  
Past-President*



Jean-Pierre Paccioni  
*Immediate Past-President*



Luigi Martini  
*Past-President*



Maurizio Battistini  
*VP European Affairs*



Giorgos Panoutsopoulos  
*VP Communications*



Brigitte Saunier  
*Treasurer*



Piero Iamartino  
*VP Technical & Professional Development*



Anni Svala  
*VP Education & Careers*

# Activities Overview

## **Education and Careers**

- *MOGLYNET Project*
- *EIPG-EPISA relations*
- *EIPG-PIER Webinars*

## **Technical**

- *Consultation document feedback*
- *EMA GMP/GDP IWG Interested Parties*

## **Thematic Areas**

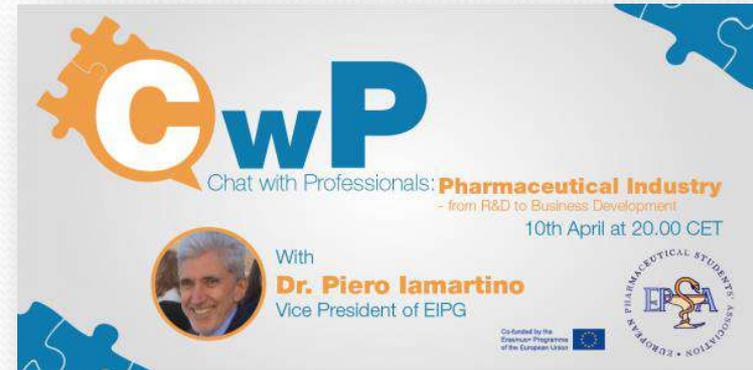
- *Delegated Regulation on Safety Features*
- *Drug Shortages*
- *Codes of Conduct*
- *Brexit*

## **Added-Value Projects**

- *Outreach*
- *Communications*

# EIPG-EPISA Relations

- EPSA and EIPG regularly join forces for online events for students, including joint Webinars, and online Chat with Professionals events.
- Regular TCs organized by Anni Svala
- EIPG is in regular contact with EPISA to provide support in the Mentoring Project, and the EPISA Career Page.
- EIPG Past-President and Fellow Luigi Martini attended the EPISA Annual Reception 2018 at the European Parliament.
- Amon Wafelman, representing NIA and EIPG, coordinated two workshops at the EPISA Annual Congress in April.



# MOGLYNET project



- Horizon 2020 MSCA joint doctoral project run by a Consortium of Universities in cooperation with Industries and Associations in the Pharma sector
- The mission is to define a **joint doctorate educational training model in Drug Discovery and Development** where Academia and Industry join their forces
- Aim is to offer an innovative PhD level training in Drug Discovery and Development to 12 Early Stage Researchers.

# EIPG-PIER Webinars



**PIER** **GPIE**  
**EIPG**

## *FMD Implementation – Insights from a National Medicines Verification Organisation*

*Leonie Clarke*

Webinar for members of EIPG  
in conjunction with  
PIER and University College Cork

[Click here to register](#)

Tuesday 25<sup>th</sup> September 2018  
at 16.00 GMT (17.00 CET)

**PIER** **GPIE**  
**EIPG**

## *Integrated Quality Management Systems*

*John Jolley FRPharmS FCOI CQP*

Webinar for members of EIPG  
in conjunction with  
PIER and University College Cork

[Click here to register](#)

Monday 15<sup>th</sup> October 2018  
at 16.00 GMT (17.00 CET)

**PIER** **GPIE**  
**EIPG**

## *Data Integrity*

*Alessandro Regola*

Webinar for members of EIPG  
in conjunction with  
PIER and University College Cork

[Click here to register](#)

Tuesday 11<sup>th</sup> December 2018  
at 16.00 GMT (17.00 CET)

# EIPG's monthly newsletter



## Technology & Production How to manage the data integrity risks

The management of data integrity risks is fundamental to ensure data are correctly handled during the entire process of pharmaceutical manufacturing. An effort that is facing the increasing complexity of IT systems

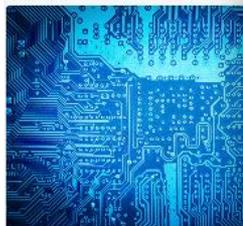
[Read more...](#)



## Politics & Business Hard Brexit, soft Brexit, no Brexit?

After the approval of the withdrawal agreement by the European Council, in UK the Parliament's vote has been postponed and the chaos is prevailing. All possibilities are currently open for the Brexit, just three months before 29 March 2019. A summary of latest events.

[Read more...](#)



## Focus on EU's Countries From Italy: The main themes discussed at the annual AFI Symposium

All main themes in the field of pharmaceuticals have been addressed during the 58<sup>th</sup> AFI Symposium, the annual meeting of the Italian pharmaceutical industry this year attended by more than 1,400 participants

[Read more...](#)

## Regulatory The use of real world data for R&D of pharmaceuticals

EMA's director general Guido Rasi is among the authors of a paper published in Clinical Pharmacology and Therapeutics, discussing from a regulatory perspective the use of real world data to boost pharmaceutical development

[Read more...](#)



## Monthly update from EIPG An Advisory Group for the education of industrial pharmacists

EIPG is planning the launch of an Advisory Group for the education of industrial pharmacists, in order to better support competences needed by the industry. Representatives of the association participated to the EMA meeting on shortages of medicines. EIPG is also collecting opinions on ICH Q12 draft guideline to be submitted to the open consultation. A webinar on data integrity is also planned for 11th December

[Read more...](#)

# EIPG QP Code of Practice



- A basic outline has been created through the collaboration of Walid El Azab (*Belgium*), Mounir Rizovsky (*Belgium*) and Carol Candlish (*Great Britain*), that takes account of the GDP aspects of the roles of a Qualified Person.
- Maurizio Battistini and Piero Iamartino, together with the collaboration of Alessandro Regola (*Italy*), have developed the document further towards its final form, extending the scope of the GMP aspects to cover the entire duties of the QP working in industry.
- The document includes a general part (Basic Requirements, General Principles) and a specific part (Areas of Responsibility)
- For each Area of Responsibility, we report excerpts of official documents and comments on how to meet, in practice, the requirements, with recommendations and suggestions.
- This specific part is a living document which can be continuously updated .

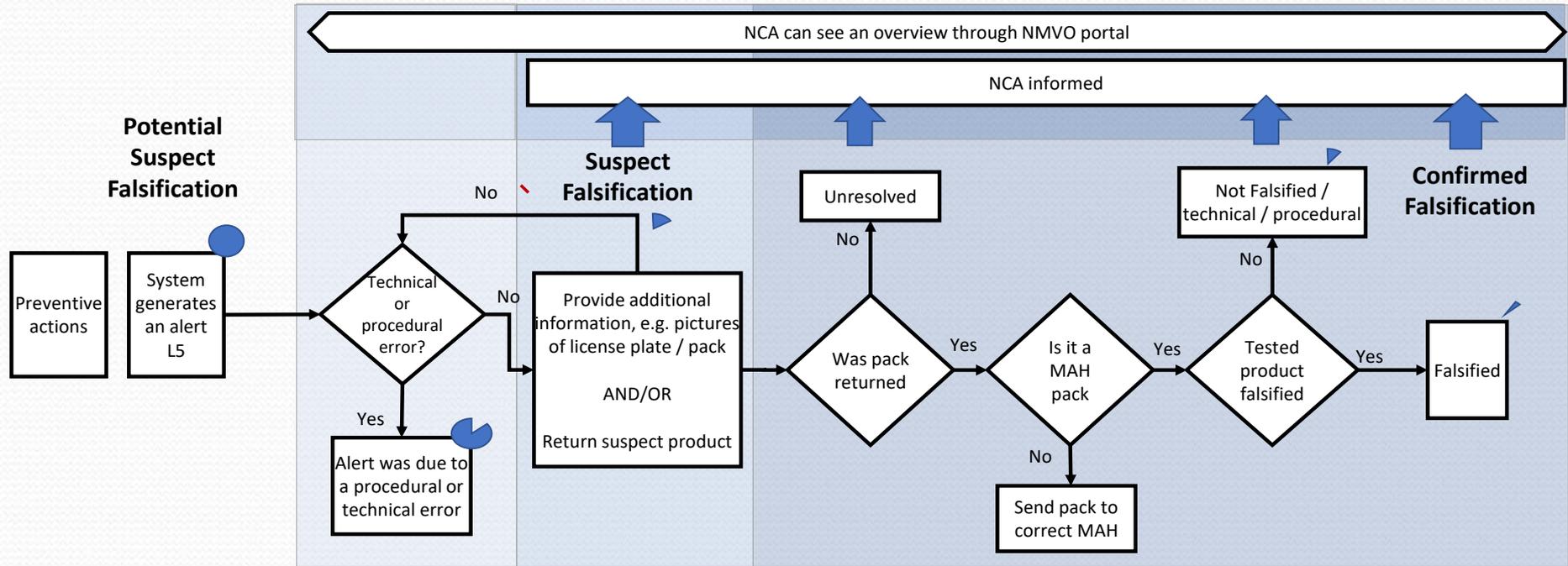
# Outreach Initiatives

- Meeting with French industrial pharmacists at the Ordre des Pharmaciens to discuss their professional challenges (*January 2018*)
- VAPI-UPIP General Assembly, with HRH Princess Astrid of Belgium in attendance to recognise VAPI-UPIP as a Royal Association (*February 2018*)
- Maurizio Battistini represented EIPG at a meeting of the European Pharmacists Forum, on the personal invitation of Dott. Ornella Barra, EPF Founder and COO WBA (*March 2018*)
- AEFI General Assembly (*May 2018*)
- Maurizio Battistini, Piero Iamartino and Claude Farrugia represented EIPG at the 58° Simposio AFI (*June 2018*)
- Jane Nicholson represented EIPG at the 78<sup>th</sup> FIP World Congress (*September 2018*)



- Un progetto piu che lungo, smisurato.
- Still many logistical issues to be solved in terms of implementation, and an impending realisation of significant workload increase post-implementation.
  - Divergences in URS implementation between Solidsoft Reply and Arvato (*PC not found, expiry date issues*)
  - Retrospective upload consequences
  - Alert management
  - Italy and Greece: the consequences of a derogation
- EIPG's role:
  - Achieving know-how through member input
  - Development of a Safety Features Qualified Person Guidance
  - Plans for a similar guide for Responsible Persons.
- Regular contact with EMVO, EMA and European Commission for clarification on issues of concern.

# Serializzazione: Ultimissime novità e aspetti critici



Note: the number of generated alerts is not know, the volume as depicted in the blue 'pies' are assumptions

# Shortage di medicinali

- EIPG forms part of a group of Joint Supply Chain Actors together with PGEU, EAHP, EIPG, EFPIA, Medicines for Europe, AESGP, EAEPC, meeting regularly to update its Joint Supply Chain Actors Statement on Information and Medicinal Products Shortages, issued in 2017.
- EIPG participated in the HMA/EMA technical meeting on availability of authorised human medicines, in November 2018
- COST Action CA15105: European Medicines Shortages Research Network - addressing supply problems to patients (Medicines Shortages)

# *HMA/EMA technical meeting on availability of authorised human medicines (8<sup>th</sup> Nov 2018)*

- Key output: *Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA).*
- **Main Questions Addressed.**
  - What is a shortage?
  - What issues should be reported by MAHs?
  - Who is responsible for monitoring supply and reporting shortages?
  - When should a notification be made?
  - Who should be notified?
  - What information should be included in notifications?

# EMA GMP/GDP IWG - Interested Parties

- Piero Iamartino and Claude Farrugia represented EIPG in multistakeholder discussions for an EMA informal meeting with “Interested Parties”
- Una discussion informale intorno alle seguenti punti
  - *Cambiamenti attesi in Eudralex Vol. 4*
  - *Implementazione GMP - Annex 1*
  - *GMP per importazione (Annex 21)*
  - *Implementazione GDP*
  - *Serializzazione e responsabilità della QP*

- Luigi Martini, Jane Nicholson, Claude Farrugia and Quynh Le regularly attend, in person or remotely, EMA Industry Stakeholder meetings on Brexit and operation of the centralised procedure for human medicinal products.
- Documents issued by the European Medicines Agency, the Heads of Medicines Agencies, the European Commission and the European Council, HM Government, and other stakeholders are being collated in a special area of the EIPG website for members.
- EIPG has joined the European Health Community, a coalition of health stakeholders whose objective is to lobby to ensure that in the area of healthcare, patients' interests shape the agenda of both negotiating parties in the Brexit process.



# *Iniziativa EIPG per la formazione universitaria*



- We want to open discussion and support universities and other educational stakeholders to develop studies of industrial pharmacy, in order to develop competencies needed when working as a professional in pharma industry
- The pharma industry constantly needs new skills to cover all the main aspects of the roles requested in the pharma industry (not only regulatory, research & development and the QP, but also market access, pharmacovigilance, operations, quality management, procurement, warehousing, distribution (GDP), financial and legal aspects).

# Iniziativa EIPG per la formazione universitaria



- We have an understanding and concern that only a part of these fields are covered by current university degrees
- Future graduates in pharmacy may no longer acquire the necessary knowledge and skills to ensure the adequate knowledge that training for pharmacists should provide, and that may furthermore hinder the access of pharmacists to professional activities in the pharmaceutical industry, without the acquirement, not only of additional professional experience but also additional higher education.