



EXCIPIENT  
LEARNING  
LAB

# Webinar



## Overview of IPEC-Americas

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Janeen Skutnik-Wilkinson, Moderna

December 11, 2024

Multiple stakeholders; **one objective.**



# Disclaimer

The views, thoughts, and opinions expressed in this presentation belong solely to the authors, and not necessarily to the author's employer, organization, committee or other group or individual.



## Priscilla Zawislak

Global Regulatory Affairs  
Advocacy Manager

IFF



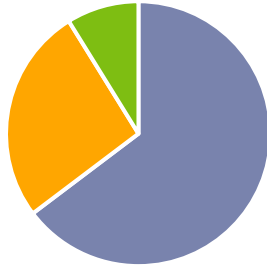
## Janeen Skutnik-Wilkinson

Director, Regulatory Intelligence  
and External Engagement

Moderna

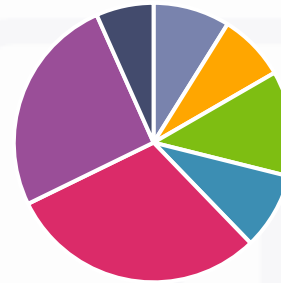
# Attendee Demographics

## Organization Type



- Excipient Manufacturer
- Excipient User
- Distributor

## Areas of Interest



- Formulation
- Research & Development
- Quality
- Procurement
- Operations/ Production
- Technical Service
- Regulatory

# Poll Question



# Poll Question

How long have you been involved with IPEC-Americas?

- A. Less than 1 year
- B. 1 - 3 years
- C. 4 - 8 years
- D. > 8 years

# Agenda and Learning Objectives

IPEC-Americas members will be provided with:

- Introduction to IPEC-Americas
- Roadmap to IPEC-Americas internal processes
- Representing IPEC
- IPEC Federation & Sister PECs



# Introduction to IPEC-Americas





# Value Proposition



Multiple stakeholders;  
**one objective.**

- ▶ **A source** for reliable regulatory information
- ▶ **A seat** at the table to discuss issues impacting your business
- ▶ **A structure** for industry collaboration for a safe & secure supply chain
- ▶ **A system** for education and cooperation to stay current on industry developments

IPEC brings together diverse stakeholders that share a common objective:  
**Safe and effective production and use of excipients.**

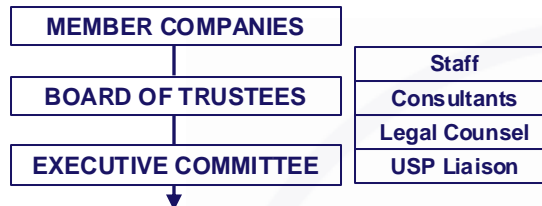
**IPEC: Collaborative solutions for excipient industry stakeholders**  
**[www.ipecamericas.org](http://www.ipecamericas.org)**

# Volunteer driven vs. Staff driven Association

- Executive Committee
- Committees
  - Standing committees
  - Sub-committees
  - Working groups, Task Teams, etc.



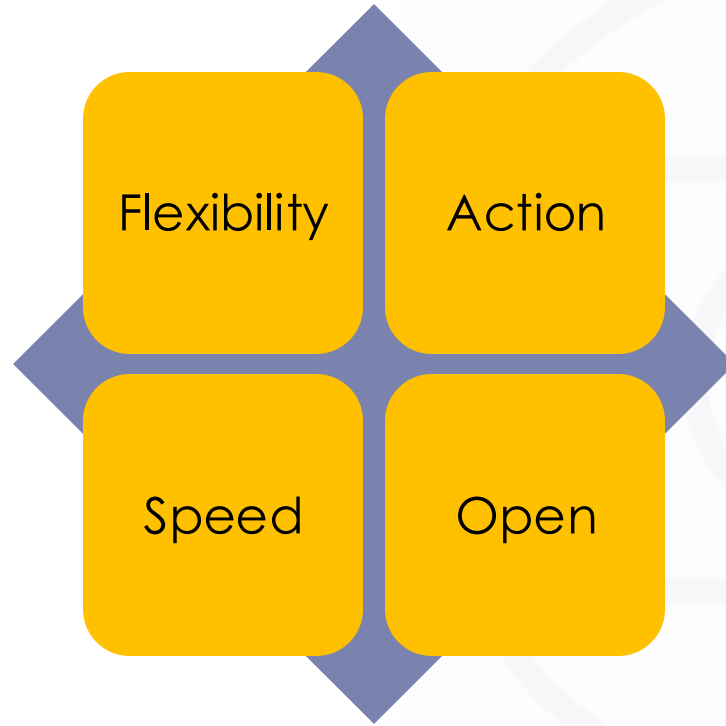
# Organization Chart



## Standing Committees and Working Groups

Doug Muse Kathryn McCullough	Candy Reynolds-Cummings Kayla Thompson Allen	Mike Cassell Elizabeth Febbo	Dave Schoneker TBD	Bob Sulouff Troy Barrix	Teresa Wegesser Alexis Smith
<b>Compendial Review/Harmonization</b>	<b>Excipient Qualification</b>	<b>GMP</b>	<b>Quality by Design Excipient Composition</b>	<b>Regulatory Affairs</b>	<b>Scientific Affairs</b>
Compendial Monographs and General Chapters	Excipient Information Package Guide (EIP)	GMP Guide	Excipient Composition Guide	FDA Inactive Ingredient Database	Novel Excipients
	CoA Guide	Stability	Quality by Design Guide	DMF Guide	
	Significant Change Guide	GDP Guide	QbD Sampling Guide		
	Quality Agreement Guide	Excipient GMP Audit Guide	Excipient Variability Guide		
	Risk Assessment Guide	Validation Guide	Technically Unavoidable Particle Profile Guide		
	Excipient Qualification Guide	Atypical Actives			
<b>Strategic Teams</b>		Excipient GDP Audit Guide			
Collaborations		Excipient GDP How To Guide			
Membership & Market Expansion					
Education					
				<b>Working Groups</b>	
				Excipient Learning Lab	
				User Relations	
				Maker and Distributor Relations	
				ExcipientWorld and ExcipientWorld Academy	

# Our Culture



# How We Work Together

We want everyone's  
opinion and input

We like to have  
multiple people  
from a company  
participate in IPEC  
activities

# How to Raise a Topic



## **Do you have a new issue or topic to raise?**

If you know what committee it belongs to you can send it to the committee chair and ask for it to be added to the next agenda

If you are unsure, send to the IPEC office and Governance or XC will discuss



## **Once the topic is brought to a committee meeting you will have the chance to propose your idea.**

If the concept is of interest to multiple companies, it can move forward



# Roadmap to IPEC-Americas internal processes



# Bylaws



- Become familiar with key articles:
  - ARTICLE VI Executive committee
  - ARTICLE VII Committees
- Libraries are located on the website – Home for guidance documents, policy documents, comments, white papers, etc.



# Policies

- Principles, rules, and guidelines formulated or adopted by an organization to reach its long-term goals
- Accessible from the web site in the document depot
- Revised when needed by Policy Review Team
- Includes procedure on document and guide review

# Opportunities

## Time Commitment

- \* Commenting Team Member
- \* Project Team or Working Group Member
- \* Committee Member

- \* Leading Commenting Team
- \* Leading Project Team

- \* Committee Chair
- \* Committee Co-Chair
- \* IPEC Officer

# Standing Committees and Liaisons



## **Standing Committees**

- Good Manufacturing Practices Committee
- Compendial Review/Harmonization Committee
- Regulatory Affairs Committee
- Safety Committee
- Quality by Design Product Development Committee
- Excipient Qualification Committee



## **Liaisons**

- USP Liaison

# Example

## **Bylaws excerpt for Quality by Design Product Development Committee**

The Quality by Design Product Development Committee is composed of pharmaceutical formulators, new product and excipient development scientists, and other experts from industry and academia to assist in the establishment of standardized decision-tree processes for developing experimental study plans to better understand the link between excipient properties and functions in different formulations and manufacturing systems. The Quality by Design Product Development Committee also coordinates the development of any guidelines which may assist in product development or formulation of new excipient or drug products.

# Budget



Committees have a budget



Use of consultants

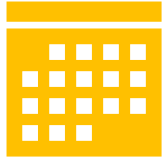


WebEx fees



Food & beverage for F2F meetings

# Agendas



- Must be available for legal and XC review and approval at least one week prior to quarterly meetings
- Email to staff at [ipeccamer@ipeccamericas.org](mailto:ipeccamer@ipeccamericas.org) for circulation

# Agendas (cont.)



Agendas containing potentially controversial topics should be reviewed by the IPEC-Americas Executive Committee and or legal counsel prior to the meeting.



Responsible individual (IPEC Staff) distributes the agenda and relevant documents (latest versions) at a minimum one week before the meeting.



See Committee Meeting Minutes Work Flow and the Management of Meetings Policy for additional information and clarification.

# Antitrust

The IPEC-Americas antitrust must be read before any meetings.

Antitrust guidelines must be abided by each IPEC-Americas member at all times, whether in person or via a teleconference or web meeting.



# Roll Call



- Conduct for in-person and online attendee
- Include the name and company
  - Note: For remote attendees, the meeting leader calls-out the individual's name and the attendee provides their company affiliation.
- Provide completed attendance sheet to staff

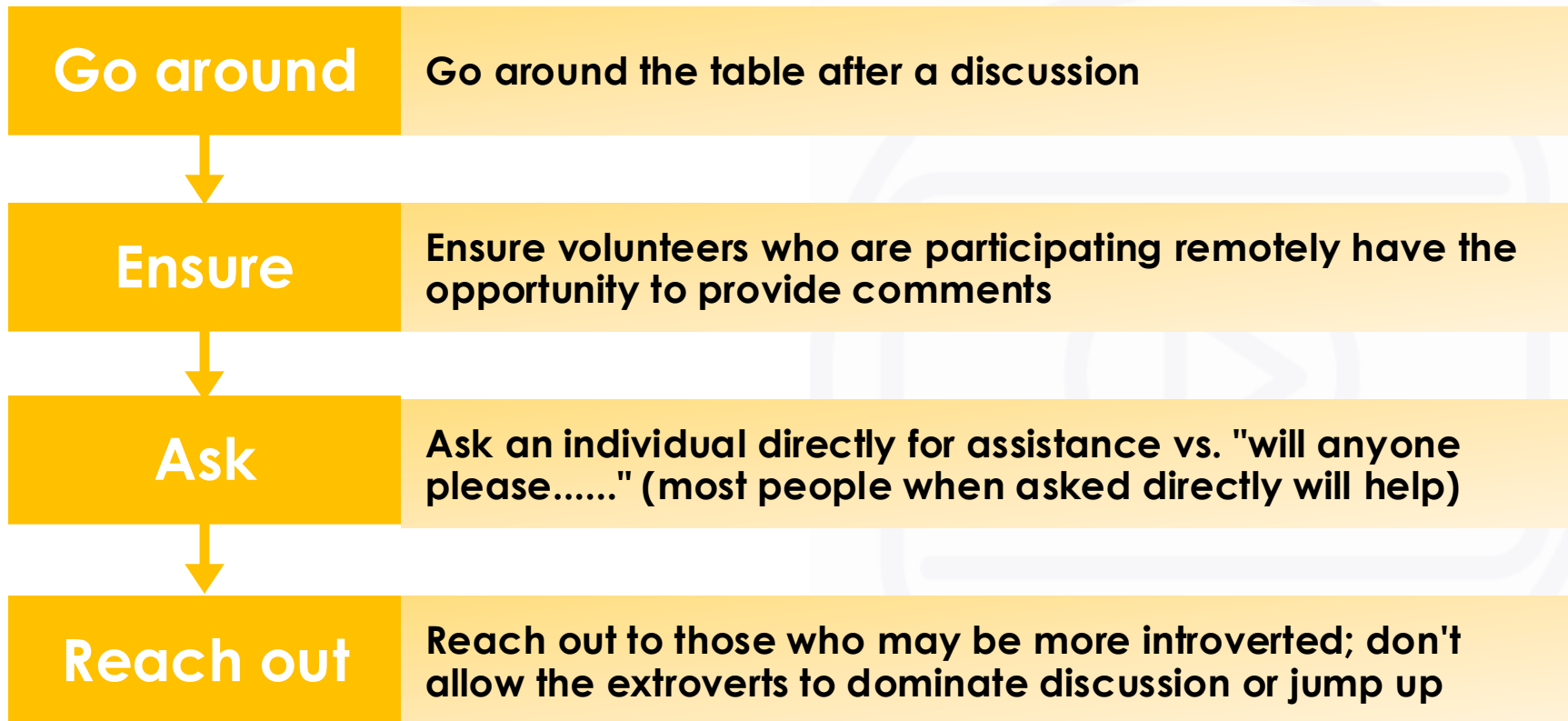
# Roles & Responsibilities

- Committee Chairs AND Vice Chairs, include:
  - Take meeting minutes
  - Send draft minutes for approval
  - Update Project Tracking Spreadsheet (PTS) quarterly
  - Suggest/draft/contribute to articles
  - Upload documents to the Committee Library

# Training & Education

- Training & Education events are sponsored by Committees
- Sponsorship means:
  - Topic is timely, relevant, of interest/soon to be of interest
  - Recommend/suggest topics for webinars, eLearning, workshops
  - Recommend SME's as appropriate

# Engaging Volunteers



# Meeting Minutes



# Commenting Teams



**Purpose** – Review and provide comments to guidance and other documents issued by IPEC, USP, FDA, etc. Typically time sensitive.



**Operation** – Review all relevant material; provide thoughtful input to the deliberations; focus on the best interests of the association; fulfill committee's goals



**Engagement** – Actively participate in the work of the committee; carry out individual assignments on time;

# Project Teams or Working Groups



**Purpose** – Perform a specific activity – usually time sensitive



**Operation** – Develop a charter or a project proposal if applicable that is approved by the XC



**Engagement** - Actively participate in the work of the team or group; carry out individual assignments; report back into the sponsoring committee or Executive Committee

# Committees



**Purpose** – Support the strategic goals and the mission of the organization



**Operation** – Meet quarterly in person, periodically as needed to accomplish goals



**Engagement** – Produce guidance, position papers, support educational activities, make recommendations



# Cross-Functional Teams

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For topics that **cut across** various committees

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Increased **transparency** and efficiency

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Current  
Topics

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Nitrosamines

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Microplastics

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Monthly Compendial Postings Review Team

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# Meeting Expectations



## **Establish Agendas for in-person and telephone/virtual meetings.**

Encourage candid participation, keep meetings on schedule, and prevent members from sidetracking or sabotaging discussion.



## **Explore ways to maximize member engagement and participation.**

All (committee) members should have an opportunity to participate in discussions and have all questions answered before any votes are taken.

# Leadership

- We can all be leaders in this organization
  - Organization Leaders (Chair, chair-elect)
  - Executive Committee
  - Committee Leaders
  - Project /Team Leaders

# Leader Behaviors

- Be accountable and accept feedback
- Respect confidentiality
- Be collaborative and inclusive
- Be clear and transparent
- As leaders we serve IPEC members

# Leader Responsibilities

- Leaders (organization, committees, teams) are responsible for ensuring that the concerns of the entire organization are heard
  - Not just their own company views
- Leaders of the organization are the voice of IPEC



# Representing IPEC



# Engaging with External Stakeholders

As an official IPEC Representative:

- Share / present the official views of IPEC
- Refrain from inserting personal or company views
- Refrain from proposing or agreeing to new topics/positions unless they have already been agreed upon by IPEC

**This is especially important when engaging with regulators and legislators.**

# Engaging with External Stakeholders

As an official representative of another trade or professional organization:

- If IPEC related matters become part of the discussion it is important to ensure that your comments are not mistaken as official IPEC requests or positions and to state that you are not speaking on behalf of IPEC

**This is especially important when engaging with regulators and legislators.**



# Engaging with External Stakeholders

Topics related to your company:

- Please ensure that if you are speaking about IPEC related matters that you are clear if you are giving the view of yourself as an individual or your company and that you are not giving the views of IPEC

**This is especially Important when engaging with regulators and legislators.**

# Engaging with External Stakeholders



- Sharing an IPEC Guidance
- Proposing a new project agreed to by the IPEC XC
- Sharing and approved IPEC position paper



- Recommending the IPEC guidance be incorporated into regulation
- Committing to a new project that the XC has not been made aware of
- Presenting an unapproved position as an IPEC position



# IPEC Federation & Sister PECs



# Who is in the Federation?



The IPEC Federation  
brings together the  
global Pharmaceutical  
Excipients Councils.



**iPEC**  
EUROPE



# Federation Organization

- Umbrella organization of each of the 5 regional IPECs
- Each association, not member companies, are members of the Federation
- Incorporated as a non-profit in Belgium and subject to EU/Belgian laws
- Members pay dues to the Federation
- 3 Staff including the Secretariat – paid positions

# Federation Organization

- Federation Board: one voting member/representative from IA, IE, IJ and IC, IPEC Federation President, Vice-President and Treasurer
- IPEC India is not a full member; no voting rights on the Board
- There may be an additional member from a regional IPEC
- Branding: “IPEC” = IPEC Federation

# 2024/2025 Officers

- **President:** Kevin Hughes, IPEC Europe
- **Vice – President:** Priscilla Zawislak, IPEC-Americas
- **Treasurer:** Hiroshi Watanabe, IPEC Japan
- **Representatives:**
  - J Skutnik-Wilkinson, IPEC-Americas
  - C. Tian, S Wang, IPEC China
  - F Milek, IPEC Europe
  - F Ohbayashi, IPEC Japan
  - K Desai, A Singh, V Metkar, IPEC India

# The IPEC Federation

- A global organization consisting of regional associations (IPEC-Americas, IPEC Europe, IPEC Japan, IPEC China and IPEC India) promoting quality in pharmaceutical excipients
- Formally created in January 2010 in Cannes, France
- Recognizes that the drug market is global, including excipient sourcing
- Builds on IPEC's '**unique**' setup of makers, distributors, and users of excipients sharing the same '**quality and safety**' vision, representing an industry speaking as '**one voice**' on common global excipient issues
- Monitors regulatory developments from multiple perspectives and geographies



# IPEC Federation Vision

Protecting patients through global partnerships in the innovation and safe supply of pharmaceutical excipients.

# IPEC Federation Mission (abbreviated)

- **To develop** and implement voluntary, harmonized guidance to ensure excipients meet appropriate standards for quality, safety, and functionality;
- **To influence** the adoption of scientific, risk-based global regulatory standards for excipients;
- **To educate** and cooperate with other organizations to advance public health on matters relating to excipients
- **To be recognized** as a professional, credible, and reliable source of information relating to excipients;
- **To establish** IPEC as the leading international organization for excipient suppliers and users of excipients.

# IPEC Federation Key Principles

## IPEC Federation Policies & Procedures Manual

- Anti-trust rules
- Code of Conduct
- IPEC Federation Positions (GMP, GDP, certification, atypical actives)
- Managing of the IPEC Federation 'brand'
- Communications
  - Internal, publications, presentations, exhibitions

# IPEC Federation Key Objectives

## Managing global regulatory expectations

- Identify emerging regulations impacting excipients
- Establish position papers on relevant advocacy activity

## Harmonisation of standards

- Work with PDG to continue the harmonisation process of pharmacopoeial monographs
- Develop global harmonised voluntary guidance

## Promoting supply chain security

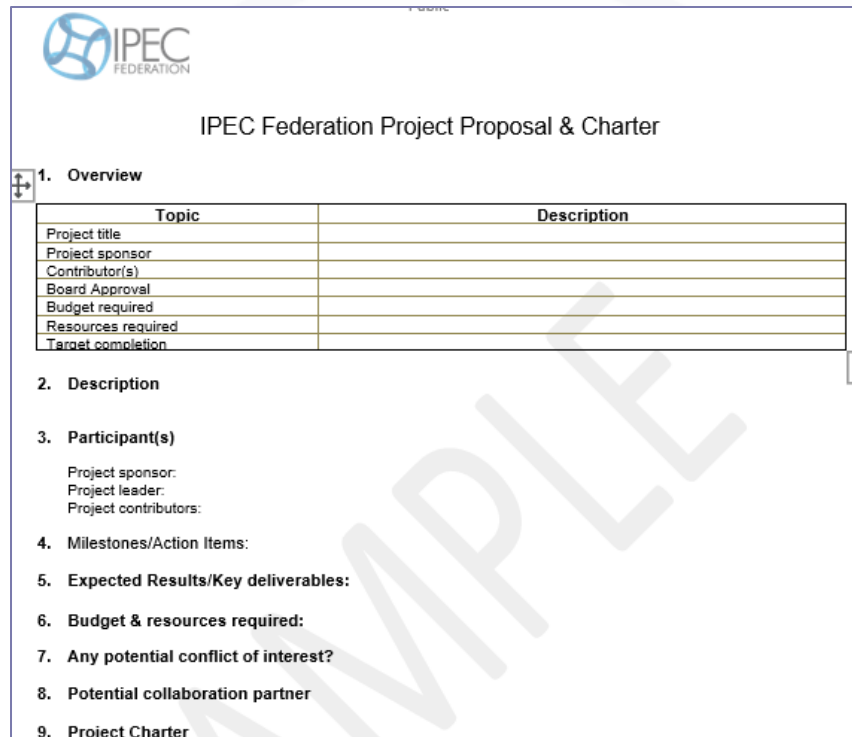
- Develop strategies for performing excipient risk assessment and management
- Collaborate with other industry organisations (e.g. ANSI, EXCiPACT® and [GAB](#) – Japan GMP auditing board for pharmaceutical excipients) on Third-party certification

# IPEC Federation – Operating Model


- Meets monthly (phone) and twice a year in person (Feb is also the Annual General Meeting)
- Meets annually with the PDG
- Annual Strategic Plan and Objectives
- Goal is to have Federation guidelines unless the topics are specific to a region
- Topics for Federation consideration are raised by regional IPECs via their representative(s)

# Federation Work Projects

- Each IPEC is given an opportunity to participate in any Federation project
- Regional IPECs may sometimes work bilaterally if a topic is only of interest to certain regions or if other IPECs defer to participate
- All projects should have a charter (template available)
- A Core and Extended team is established from volunteers from each IPEC interested in participation



The image shows a template for an IPEC Federation Project Proposal & Charter. It includes the IPEC Federation logo at the top left. The title 'IPEC Federation Project Proposal & Charter' is centered. Below the title, there is a section for '1. Overview' which contains a table with two columns: 'Topic' and 'Description'. The table has seven rows for 'Project title', 'Project sponsor', 'Contributor(s)', 'Board Approval', 'Budget required', 'Resources required', and 'Target completion'. Below the table, there are sections for '2. Description', '3. Participant(s)' (with sub-sections for Project sponsor, Project leader, and Project contributors), '4. Milestones/Action Items:', '5. Expected Results/Key deliverables:', '6. Budget & resources required:', '7. Any potential conflict of interest?', '8. Potential collaboration partner', and '9. Project Charter'.

 IPEC  
FEDERATION

IPEC Federation Project Proposal & Charter

1. Overview

Topic	Description
Project title	
Project sponsor	
Contributor(s)	
Board Approval	
Budget required	
Resources required	
Target completion	

2. Description

3. Participant(s)

Project sponsor:  
Project leader:  
Project contributors:

4. Milestones/Action Items:

5. Expected Results/Key deliverables:

6. Budget & resources required:

7. Any potential conflict of interest?

8. Potential collaboration partner

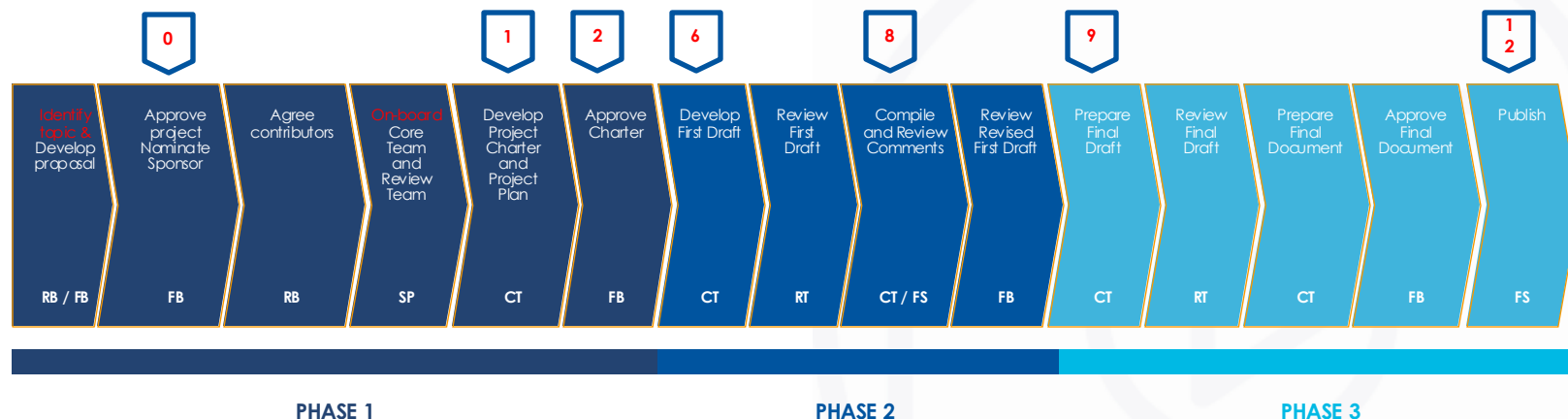
9. Project Charter

# Participation in Federation Meetings/Projects

- Federation projects take into consideration that each regional IPEC has its own by-laws, operating models and committees.
- Project timelines should accommodate this to the extent possible, e.g. turnaround time for comments, time/frequency of meetings, participants.
- Cultural awareness – many different cultures, business models, expectations for interactions with other IPEC members and regulators, expectations for documentation, language differences (English is not a first language for most), more formality.
- Any presentations given on behalf of the Federation must be approved by the Board in advance.

# Document Development & Review Process

## Critical milestones (months)



## Actors involved

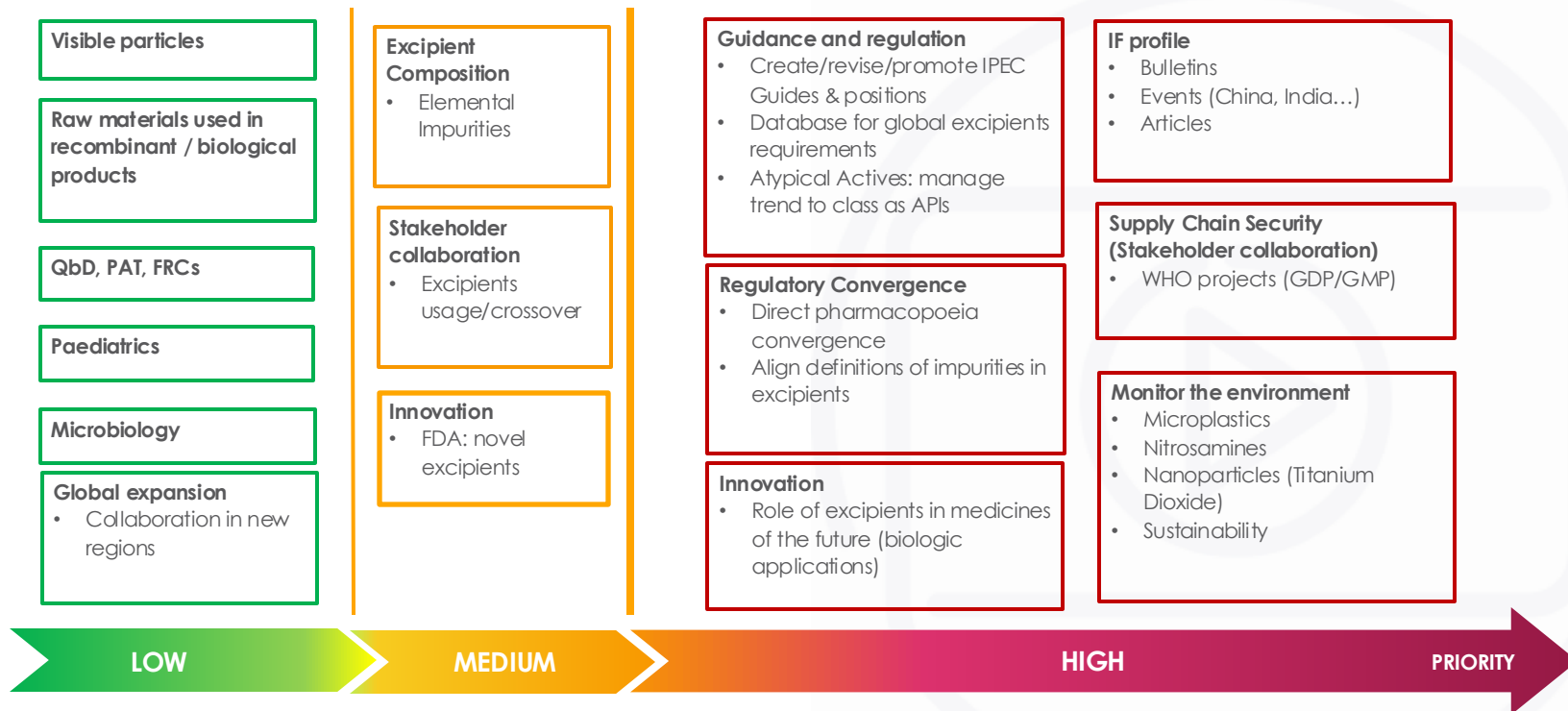
FB: Federation Board  
RB: Regional PEC Board

FS: Federation Secretariat  
SP: FB Sponsor

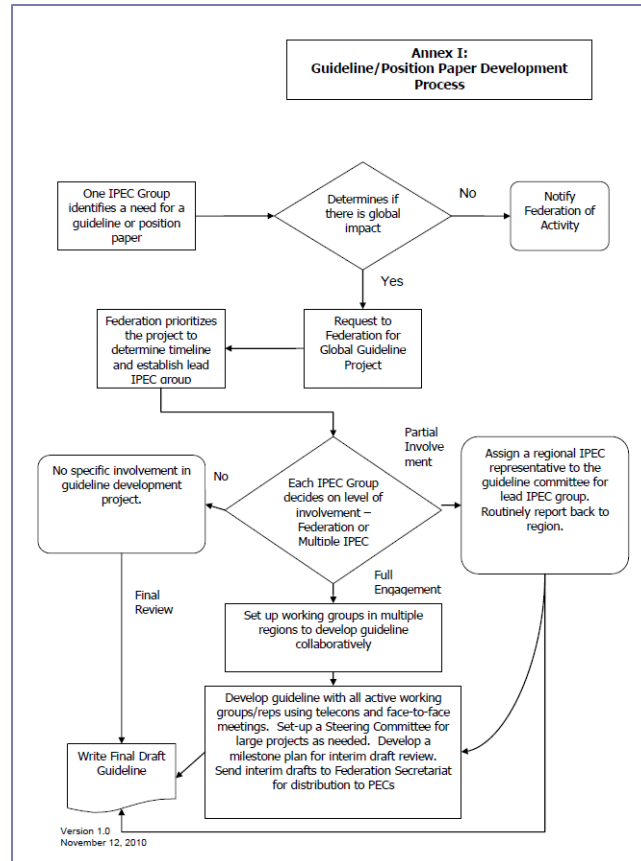
CT: Core Team  
RT: Review Team



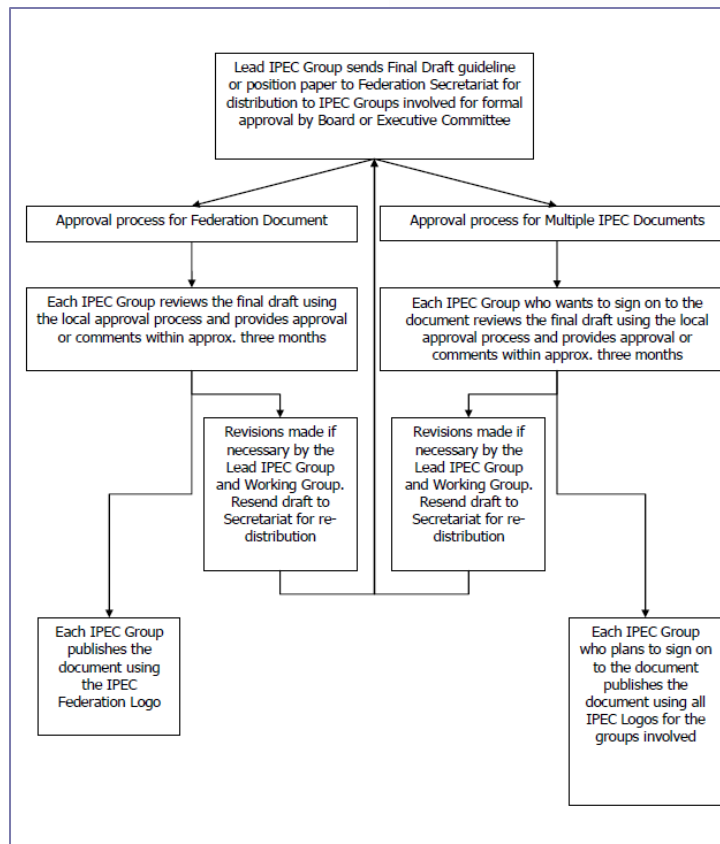
# 2024 Strategic Focus and Priority Objectives



# Guideline Process



# Guideline Process (cont.)



# Federation Projects

IPEC-Americas committee activities may also support Federation projects and activities as appropriate

Engagement of other PEC's is a priority when a project is of global scope

Committee Chairs must consider if a guide, white paper or other position may have global concern and if so, ensure that the IPEC-Americas Chair and Federation Chair are aware

Federation activities should also be identified on the PTS (Project Tracking Spreadsheet)

IPEC Federation is an observer member of the ICH

# Global IPEC Organizations

- IPEC-AMERICAS
- IPEC Europe
- IPEC Japan
- IPEC China
- IPEC India

Note: All are organized differently, have different committee and leadership structures and different fee structures.

# Considerations



- Broad cultures across sister PECs and Federation
- Written & verbal communication



# IPEC-Americas & IPEC Europe Collaboration



# Bi-lateral Collaboration



- IPEC-Americas/IPEC Europe
  - Work collaboratively bilaterally on a variety of topics



# Questions



# Presentation Evaluation

Your opinion matters.  
Thank you for your  
feedback!



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[IPECAmericas.org](https://IPECAmericas.org)

[Education.IPECAmericas.org](https://Education.IPECAmericas.org)

[ExcipientWorld.org](https://ExcipientWorld.org)

Multiple stakeholders; **one objective.**

