

OVERVIEW OF ITFG/IPAC COLLABORATION

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Introduction

*ITFG/IPAC
Collaboration*

ITFG

The Inhalation Technology Focus Group (ITFG) of the American Association of Pharmaceutical Scientists is comprised of pharmaceutical scientists who seek to foster and advance the art and science of pharmaceutical aerosol products, aerosol technology and related processes

IPAC

The International Pharmaceutical Aerosol Consortium (IPAC) is an association of companies that develop and manufacture orally inhaled and nasal products for local and systemic treatment of asthma, chronic obstructive pulmonary disease (COPD), rhinitis, and migraine, as well as new products for non-respiratory disease indications such as diabetes

DRAFT FDA GUIDANCES FOR OINDP

Draft Guidances for Industry:

- 1) *Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products Chemistry, Manufacturing, and Controls Documentation;*
- 2) *Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products Chemistry, Manufacturing, and Controls Documentation; and*
- 3) *Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action*

PERSPECTIVE OF ITFG and IPAC

ITFG and IPAC:

- share FDA's goal of assuring the highest levels of safety, efficacy and quality of OINDP and making these products available to patients expeditiously
- recognize the value of having OINDP guidance documents to facilitate the development and approval of new medications, but believe that differing views surround CMC and BA/BE issues
- believe that these differences need to be resolved through the process of a science-based dialogue so that the OINDP Guidances can bring maximum value to regulators and industry, and most of all, to patients and physicians

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BACKGROUND ON THE COLLABORATION

June 1999: AAPS/FDA/USP Workshop on OINDP Regulatory Issues

- IPAC presents a Statement proposing a consensus building process
- The ITFG endorses IPAC's Statement
- The Agency agrees to consider IPAC's proposal further

September 1999: ITFG and IPAC agree to undertake a data-driven collaborative effort

The objectives of the Collaboration are to:

- utilize the combined expertise and experience of scientists from IPAC Member Companies and AAPS Inhalation Technology Focus Group
- expand the knowledge base of the relevant science of OINDP
- facilitate common Understanding on CMC and BA/BE issues in order to provide the Agency and the Subcommittee with timely technical reports and recommendations for consideration during the Subcommittee's deliberations

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FRAMEWORK OF THE COLLABORATION

The ITFG/IPAC Collaboration is overseen by the ITFG/IPAC Steering Committee

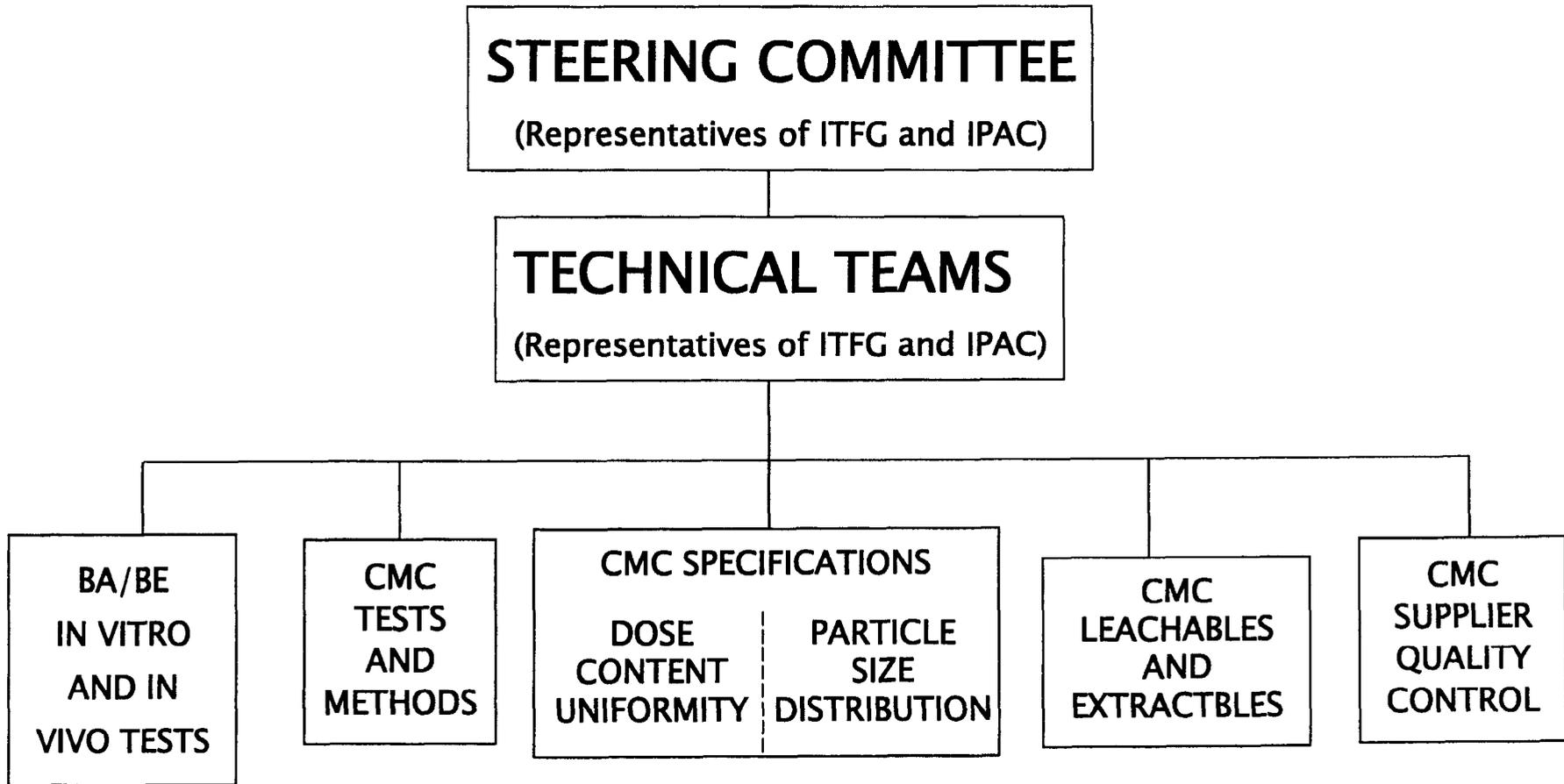
The Collaboration includes the following five Technical Teams:

- BA/BE In Vitro and In Vivo Tests Technical Team
- CMC Specifications Technical Team
- CMC Tests and Methods Technical Team
- CMC Supplier Quality Control Technical Team
- CMC Leachables and Extractables Technical Team

Technical Teams are in the process of collecting data and scientific information to investigate selected BA/BE and CMC issues in the draft Guidances

Steering Committee provides guidance to Technical Teams and reviews the findings

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PARTICIPATION IN THE COLLABORATION

Approximately 85 individuals and more than 20 companies are participating in the ITFG/IPAC Collaboration. Participants are from the following companies/institutions:

3M Pharmaceuticals	Inspire Pharmaceuticals
Agouron	IVAX
Aradigm	Kos Pharmaceuticals
AstraZeneca	Lovelace Respiratory Institute
Aventis	Magellan Laboratories
Bespak	Pfeiffer
BI Roxane	Presspart
Boehringer Ingelheim	Primedica
Dura Pharmaceuticals	Schering-Plough
Eli Lilly	Trudell Medical
Glaxo Wellcome	University of Rhode Island
Inhale Therapeutic Systems	Valois

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WORK OF TECHNICAL TEAMS

In separate presentations today, leaders of the ITFG/IPAC Technical Teams will:

- provide an overview of the work of each Technical Team

and

- describe the Collaboration's commitment to contribute constructively to the deliberations of the OINDP Subcommittee and the Agency's development of the OINDP Guidance documents

RECOGNITION OF AGENCY'S COMMITMENT TO IMPROVING QUALITY OF OINDP

- ITFG and IPAC recognize and appreciate the significant effort made by the Agency to issue the draft product quality OINDP Guidances
- ITFG and IPAC strongly support the creation of the OINDP Subcommittee and are pleased to be able to participate in today's meeting
- We thank the Subcommittee and the Agency for considering our comments and proposals