

Ph. 14054

Product Quality Research Institute

Current Status

Tobias Massa, Ph.D.
Executive Director,
Eli Lilly and Company
Chair,
Scientific Steering Committee

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BY-LAWS

- **Approved by S/C on 6/10/99**
- **Not-for-profit, non-stock, tax-exempt entity incorporated in Virginia (8/2/99)**
 - **Section 501(c)(3) of IRS Code**
 - **"...serve as a forum for academia, industry and FDA to work cooperatively to conduct pharmaceutical product quality research and to support development of public standards..."**
- **Scientific research with regulatory end points with ultimate goal of appropriately decreasing regulatory burden on FDA and Industry**

By-Laws

- **Board of Directors**
 - **Administrative management and operation**
 - **Collection and disbursement of Funds**
 - **5 members**
 - **3 appointed by AAPS Executive Council**
 - **2 recommended by Steering Committee**
 - **Chair appointed by AAPS Executive Council**
- **Executive Secretary**
 - **Liaison between Board and S/C**
 - **Maintain records, arrange meetings, minutes, etc.**
 - **Appointed by Board, approved by S/C (2/1/00)**

Board of Directors

Kenneth R. Heimlich -- Chair	(AAPS)
Gilbert S. Banker	(AAPS)
Jerome P. Skelly	(AAPS)
William Bradley	(S/C)
Tobias Massa	(S/C)

By-Laws

- **Steering Committee**
 - **develop specific mission; set scientific priorities**
 - **review research outcomes**
 - **assess overall impact of scientific activities**
 - **determine need for continuing activities and/or modifying PQRI process**
 - **Sole authority over all scientific activities**
 - **Recommends project funding to Board of Directors**

By-Laws

- **Steering Committee (continued)**

Eric Sheinin

FDA

Larry Augsburger

AAPS

Ed Fry

PDA

Bill Bradley

CHPA

Alice Till

(GPIA)

Chris Sizemore

(NPA)

Bob Milanease

(NADM)

Tobias Massa

PhRMA -- Chair

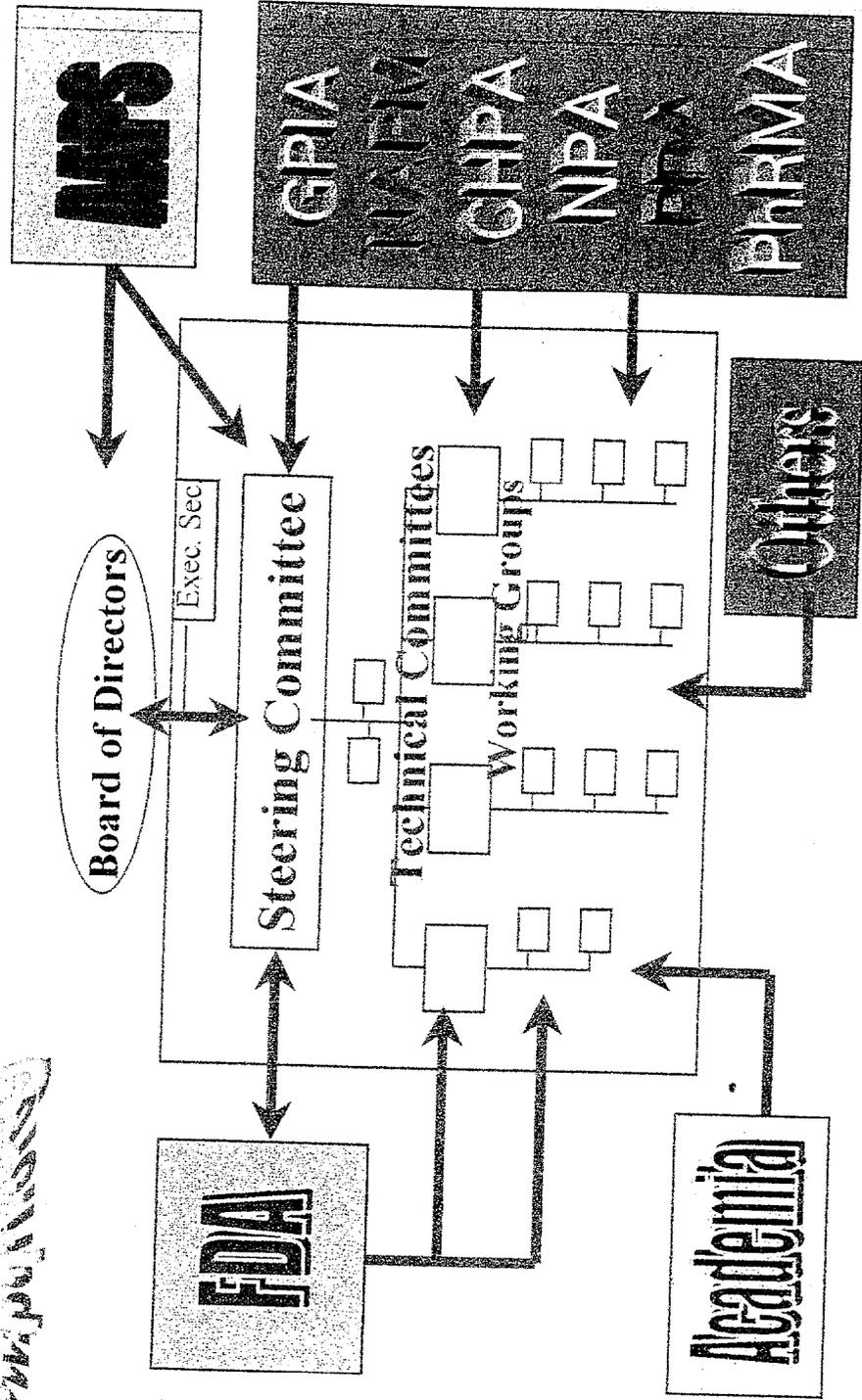
TBD

IPEC (non-voting)

} 1 vote

PQRI: Members and Organization

www.pqri.org



PQRI Process

- 1. FDA presentation of Agency PQRI-related research and integration with Technical Committee proposals**
- 2. Technical Committee presentation (11 "projects")**
- 3. Steering Committee endorsement**
- 4. S/C circulates plans to constituent organizations to solicit W/G members for T/C's**
 - time, effort, knowledge considerations**

PQRI Process

- 5. T/Cs choose W/G members from recommendations**
- 6. S/C approves W/G composition**
- 7. W/G develops specific proposals/protocols**
- 8. Review and approval by T/C, S/C**
- 9. Funding by Board of Directors**

Working Group Proposals

- 1. Hypothesis and Background**
- 2. Research Plan**
 - Data dredging vs. prospective research**
 - Who is doing the work**
 - Where is work to be conducted**
 - Sweat equity vs. academic bids vs. FDA CRADA**
- 3. What regulation or guidance is impacted by this research?**
 - Current guidance/regulation**
 - Proposed change if research is "positive"**
 - Impact of change on FDA/Industry**

Study Results

1. **W/G completes report and makes guidance/regulation recommendation**
2. **T/C reviews, approves and sends to S/C**
3. **S/C reviews, approves and sends to FDA**
4. **FDA reviews and**
 - a. **accepts conclusions/recommendations → changes regs/guidance**
 - b. **rejects conclusions/recommendations →**
 - **no change to regs/guidance**
 - **provides written explanation to S/C**

Current Research Focus

- **Drug Substance Technical Committee**
 - **Chairperson: Steve Byrn**
 - **Adherence to CGMPs and a critical comparison of the analytical results encompassing specifications, impurity profile, and relevant physical properties will be adequate to show unchanged identity, strength, quality, purity, and potency of a drug substance in the presence of pre- and post approval changes in 1) manufacturing scale, site, equipment, controls and process; 2) route of synthesis; 3) packaging; 4) supplier(s) of drug substance (DSTC Meeting 28 May 1999).**

Current Research Focus

- **Drug Product Technical Committee**
 - **Chairperson: Sid Goldstein**
 - **Adherence to CGMP's, which include validation, and appropriately established product specifications are sufficient to assure consistent quality and performance (or equivalence) of drug products that are manufactured at different locations using alternate pharmaceutical unit operations, excipients, and container/closure systems (DPTC Meeting 12 May 1999).**
 - **Blend uniformity**
 - **Manufacturing changes to IR Solid Dosage forms**
 - **Packaging changes**

Current Research Focus

- **Biopharmaceutics Technical Committee**
 - **Chairperson: Open**
 - **In vitro drug release and other appropriate physico-chemical product tests can be developed to assure equivalent rate and extent of drug absorption from pharmaceutical equivalent dosage forms (BTC Meeting 5 April 1999).**
 - **In Vitro Methods for Bioequivalence Assessment of IR Solid Dosage Forms**
 - **Methods for Bioequivalence Assessment of Topical Products**
 - **Methods for Bioequivalence Assessment of Oral/Nasal Inhalation Products**

Current Research Focus

- **Science Management Technical Committee**
 - **Chairperson: Open**
 - **The goal of this technical committee is to develop strategies that maximize the efficiency of the processes that produce an optimally performing drug product that meets public health objectives for identity, strength, quality, purity, and potency (SMTC Meeting 4 November 1998).**
 - **Process mapping (CMC & Biopharm.)**

Blend Uniformity Analysis

- 1. Review current regulatory practice of blend uniformity.**
- 2. Provide opportunity to discuss scientific comments on the draft guidance.**
- 3. Identify and provide scientific justification for changes in regulatory practices.**
- 4. Provide scientific understanding of blending process and blend uniformity testing.**
- 5. Identify issues related to blend uniformity testing and develop approaches to address these issues.**
- 6. Identify methods for assessing blend uniformity.**
- 7. Discuss and rationalize areas where blend uniformity can be eliminated and areas where it will be helpful.**

Blend Uniformity Analysis

Blend Uniformity Working Group

Pedro Jimenez

Garth Boehm

Thomas P. Garcia*

Jean-Marie Geoffroy

Gerald J. Mergen

Fernando J. Muzzio

Al Nyhuis

James K. Prescott

Jozef H.M.T. Timmermans

John Clark

John Dietrick/

Muralida Gavini

Eli Lilly & Co.

Faulding Inc.

Glaxo Wellcome, Inc.

Abbott Laboratories

McNeil Consumer Healthcare

Rutgers University

Geneva Pharmaceuticals, Inc.

Janike & Johnson, Inc.

Merck & Company Inc.

Office of New Drug Chemistry, CDER

Office of Compliance

Adhoc Statistician from the PhRMA Statistics Working Group

Jerry Planchard

Aventis

*Thomas P. Garcia is recommended to be the Chairperson of this working group