

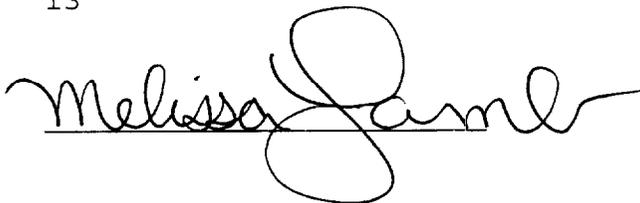
M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: February 11, 2000
To: Dockets Management Branch (HFA-305)
From: Melissa Lamb
Office of Generic Drugs
Subject: Project Management in the Division of Bioequivalence

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

Title of Presentation: Project Management in the Division of Bioequivalence
Presented for: National Pharmaceutical Alliance Fall Meeting
Date Presented: 10/18/99
Presented by: Lizzie Sanchez, Pharm.D.
Number of Pages: 13



Attachment

90S-0308

M678

Project Management in the Division of Bioequivalence

**Lizzie Sanchez, Pharm.D.
Special Assistant to Director
Division of Bioequivalence
Office of Generic Drugs**

Outline

Organizational Structure

Specific functions

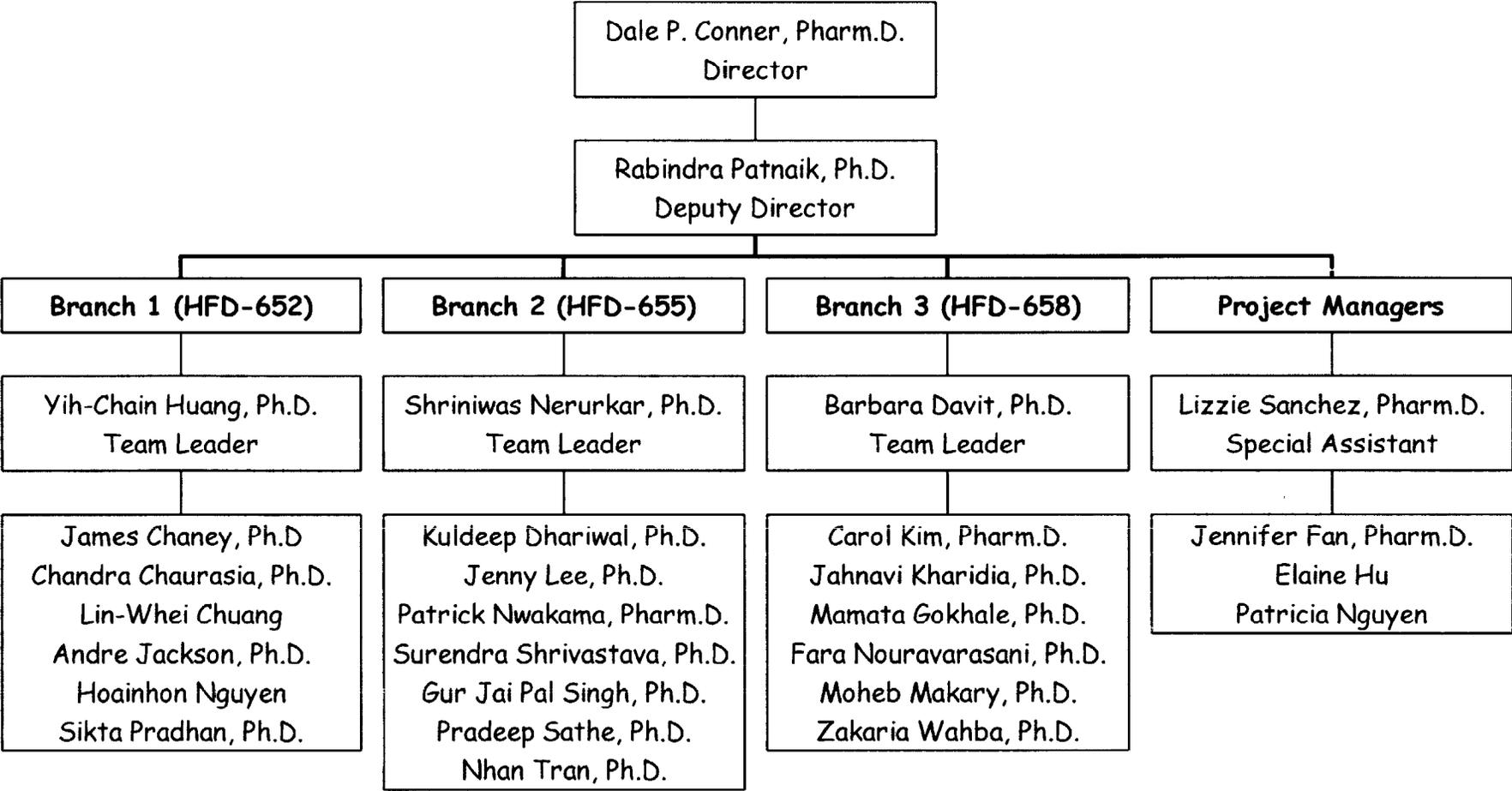
Review Documents

Review Process

DSI Inspections of clinical and analytical sites

Process Improvements

Division of Bioequivalence



Specific Functions

Management of Bio Review Process

Regulatory Guidance

Facilitation of Meetings/Teleconferences

Documentation of DBE interactions

Approvals Meetings

Tracking of Electronic Submissions

Tracking of DSI Inspections

4 Division Directors Meetings

Review Documents

- | Original and supplemental ANDA's
- | Bio-IND's (5)
- | Protocols (40)
- | Controlled Correspondence (270/60%)
- | Citizen's Petitions (24 pending/12 Bio)
- | DSI Reports

Review Process

Assign review documents as per “first-in first-reviewed” policy (PPG #42-95)

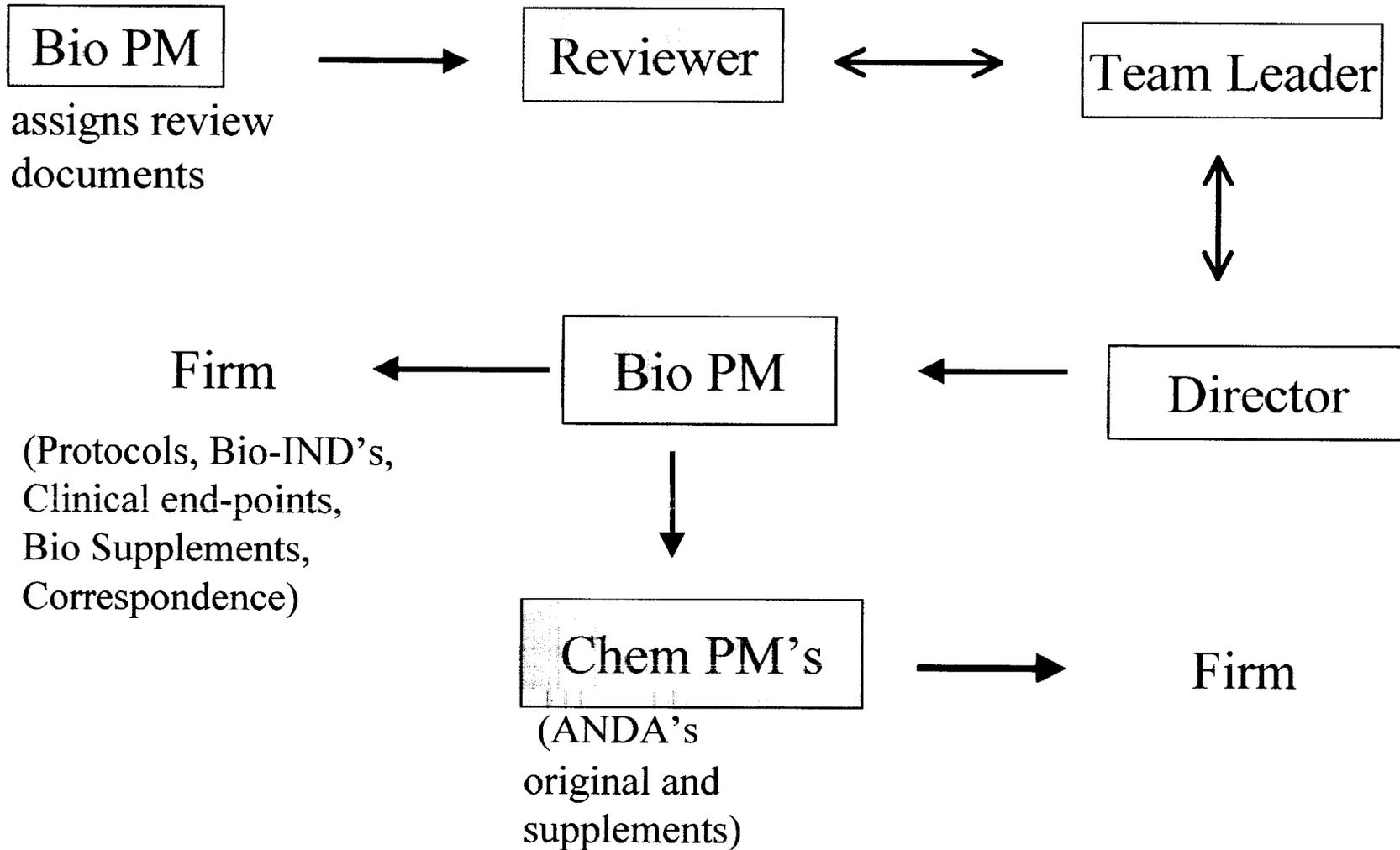
Request telephone amendments

Document in internal databases status of the Bio review

Forward bioequivalence reviews and comments to Chem PM's

Prepare comment letters for protocols, Bio-IND's & Supplements, correspondence

Review Process



DSI Inspections

Sends inspection request of clinical and analytical sites to the Division of Scientific Investigations (DSI) (first site and directed inspections, history of data integrity problems)

Receives DSI reports for action

Maintains a database of inspectional hx

Communicates outcome of inspections to Office management

Process Improvements

Controlled correspondence

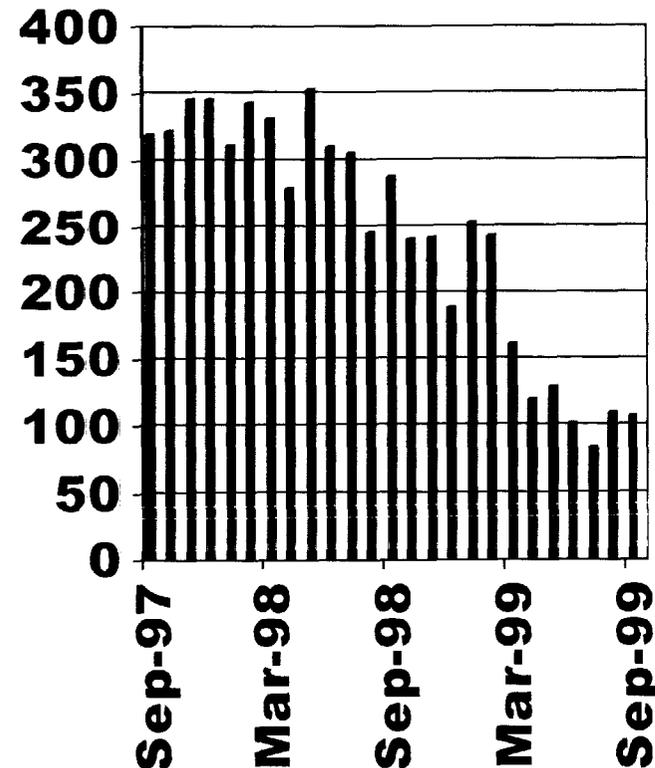
Increased project management staff

- || Routine requests of telephone amendments
- || Improved communication within and outside the Office
- || Faster processing of submission

Division of Bioequivalence Pending Workload

Number of ANDA-related submissions to review have decreased from 300's to 100's.

Bio review starts as soon as an ANDA is filed by Regulatory Support Branch



Things you can do to expedite the review

Information such as lot #, potency, expiration date, dissolution methods, SOP's should also be included in Bioequivalence review copy

Long-term stability data of plasma samples

Supplements - in-vivo studies, changes in formulation, changes in dissolution methods, new strengths

Project Management Staff

| Lizzie Sanchez, Pharm.D.

| Elaine Hu

| Jennifer Fan, Pharm.D.

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For Information

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