

P. Michael Dubinsky
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Senior Quality and Compliance Leader with a sound record of managing programs, resolving complex issues and applying an authoritative approach to achieving and sustaining regulatory compliance. Applies experience and insight gained from FDA and private sector to instill a quality mindset and identify and fix compliance gaps to reduce statutory exposure. Shares wisdom and guidance to enhance training, application submission and statutory reporting.

Professional Experience

Independent Consultant, Fremont, CA

2007-2008

Provide GXP compliance and quality consulting services to pharmaceutical and biotech firms.

- Conducted quality audits of internal processes and external suppliers.
- Conducted and reported on evaluations of compliance exposure and risk.
- Drafted standard operating procedures
- Developed and conducted training sessions for management and operational staff.
- Served as an expert witness.
- Instructor in UC Berkeley Extension programs addressing compliance, regulatory audits and quality matters.

Novartis (Chiron), Emeryville, CA

2003-2006

Senior Director, Development QA, Biopharma

Responsible for Quality Assurance (QA) programs in the Good Clinical Practice (GCP), Good Laboratory Practice (GLP) and Software System areas.

- Managed Audit Program that covered investigational sites, Contract Research Organizations (CROs), documents and systems. Approximately 120 audits conducted per year to effectively address potential compliance risks.
- Designed, implemented and delivered GCP and inspection readiness training for in-house Development staff and Clinical partners to create a quality culture and proactively identify problems.
- Served as the Quality Assurance approver for SOPs, validation deliverables, GLP compliance to ensure conformance with regulatory and business expectations.
- Coordinated pivotal decision on software compliance, chartered and chaired corporate EDMS committee and prepared decision papers on compliance matters.

Wyeth, Radnor, PA

2001-2003

Assistant Vice President, Compliance, Compliance Operations

Supervised Compliance Team composed of five senior personnel.

- Coordinated sustainable compliance activities with sites to remediate FDA inspectional observations in the areas of training, product complaints, recalls, and record keeping
- Chartered and championed a laboratory compliance team encompassing more than six sites to address matters common to each, such as meeting GMP training requirements.
- Created GMP Awareness program in Good Documentation Practices (GDP) and delivered it to over 2500 employees at seven sites to prevent repetition of serious GDP errors.
- Drafted compliance policies and SOPs for Recalls & Transmissible Spongiform Encephalopathies which were finalized and adopted.
- Processed complex Compliance Hotline matters to successful resolution avoiding adverse situations.

SangStat Medical, Fremont, CA**2000-2001****Vice President, Compliance, Quality & Regulatory Affairs**

Supervised and directed staff located in Global Quality & Regulatory Affairs Units-UK, USA, and France. Guided Product Application Program with FDA, Canada, UK covering six INDs, BLA, 510(k)s, IDE, CTX

- Represented firm at meetings with FDA concerning complex compliance matters, including recalls and withdrawal of an ANDA. Serious legal penalties were avoided.
- Coordinated overall QA program addressing Error Reporting, Supplier Qualification, Change Control, Manufacturing Discrepancies, Recalls, Internal audit for corporate compliance.

Alpha Therapeutic, Los Angeles, CA**1998-2000****Director, Reg Affairs & Compliance**

Directed Donor Center QA activities; Supplier Qualification; Device QA, hosting inspections, meetings with FDA and Risk Assessments.

- Coordinated Submission of successful FDA License Applications, amendments, response to compliance correspondence, ISO Certification and CE Mark authorizations
- Developed Policies and Procedures for a range of topics such as Donor Center QA, Disposition of adulterated materials, change control, non-conforming plasma, recalls which were adopted
- Presented GMP compliance training to all incoming supervisors

Food and Drug Administration (FDA)**Deputy Director, Office of Compliance, CBER, Rockville, MD****1990-1998**

Served as "COO" for three Division Office with 62 FTEs. Oversaw resources, budget, policy development, compliance decisions, and program direction. Acting Director for one year.

- Represented Office on policy setting groups, Blood Enforcement, Product Advertising, Tissue Workgroup, HCFA Liaison, Blood Import, EU Drug Inspection MRA Working Group, FDA Field – HQ Relationships
- Contributed to FDA policies on data integrity, home AIDS testing, software regulation and error reporting
- FDA representative at congressional hearings, industry conferences and legal actions

Director, Office of Compliance**1988-1990****Division of Regulations and Bioresearch Monitoring, CBER, Rockville, MD**

- Program Manager for CBER rules and FR notices concerning Biological Products.
- Re-established biologics BiMo Compliance and Inspection program activities for sponsors, investigators, laboratories and IRBs involved in clinical development.
- Coordinated two successful high visibility investigations involving AIDS and transplantation.

Chief, Case Management Branch, Office of Compliance**1985-1988****Center for Devices and Radiological Health, Silver Spring, MD**

Managed the CDRH legal action review program for recommended legal action injunctions, prosecutions, seizures, compliance letters, and detentions. Coordinated Expert Witnesses support for legal actions. Participated in numerous Industry conferences and FDA initiatives as spokesperson for CDRH Compliance initiatives.

Education

BS, Microbiology, University of Maryland

Training and Development

- Foundation for Advanced Education in the Sciences, Inc. (The Graduate Program at N.I.H.)
 - a) Basic Principles of Immunology and Hypersensitivity b) Introductory Virology
- Food and Drug Law Course (George Washington University)
- Food and Drug Law Course (Dickerson)
- Policy Making in the Federal Government (University of Southern California, Washington DC)
- Decision Making in Regulatory Agencies (University of Southern California, Washington DC)
- Executive Leadership Program (Wyeth)
- GMP for Supervisors (Wyeth)
- Quality Systems for Executive Management (Chiron)

Professional Presentations Since 2000

- Instructor, UC Berkeley Extension
Clinical Research Conduct Management, Audit & Compliance, Module 2006 & 2007
- Preparing For an FDA Inspection
CRA/Clinical Trial Monitor Workforce Conference, Philadelphia, PA 2006
- Managing Compliance
Quality & Compliance Executive Forum, Pacesetter Group 2002
- Senior Administrators Compliance Forum, ISRA Annual Conference 2001

Recognitions

- Training Excellence 1999
- Distinguished Service 1998
- Outstanding Service 1998
- Commendable Service 1995
- Award of Merit 1995
- Group Recognition 1994
- Commendation Medal 1994