

# OCRA

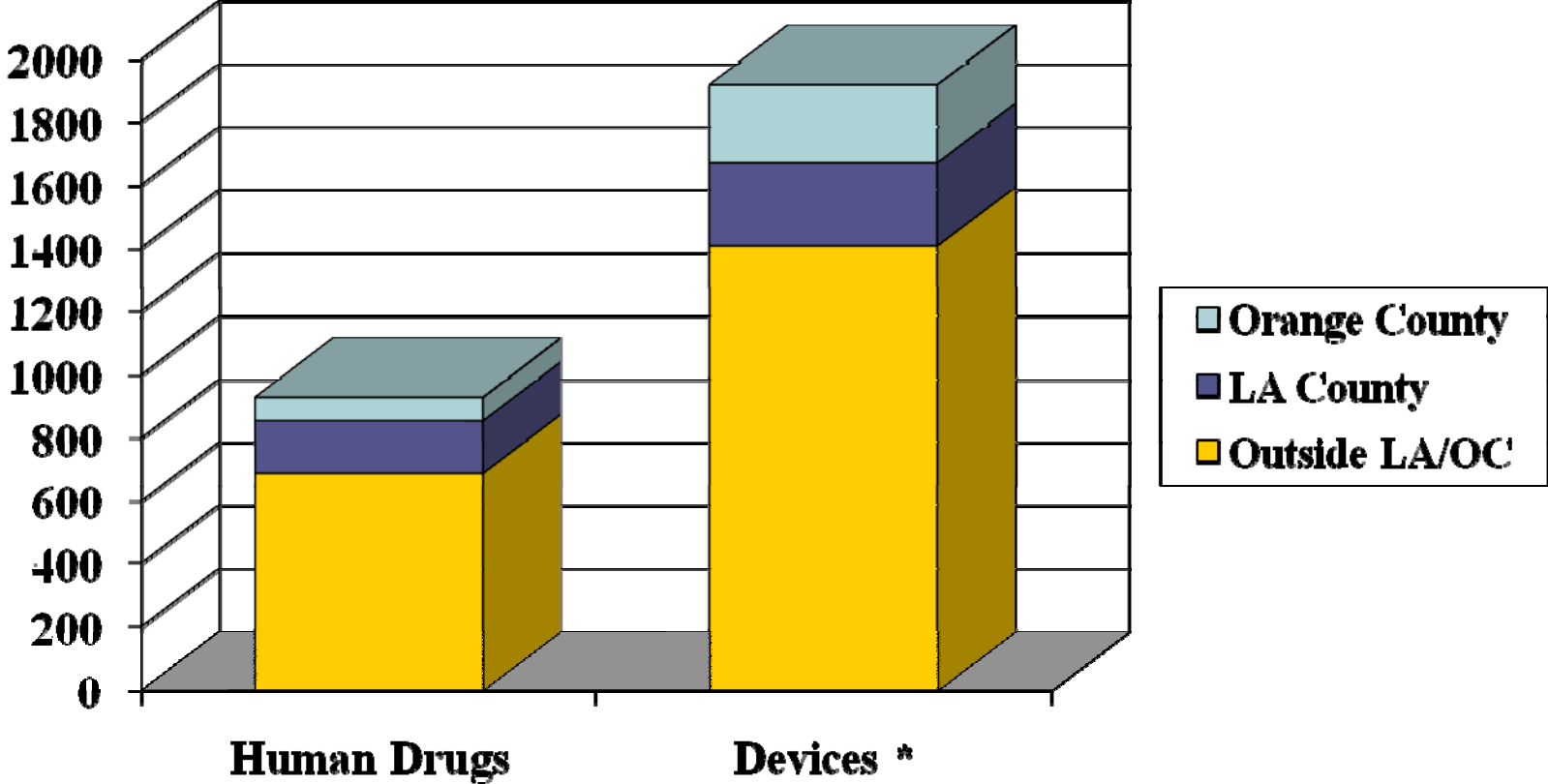
## Orange County Regulatory Affairs Discussion Group

Christine Posin, President  
June 9, 2008

# What is OCRA?

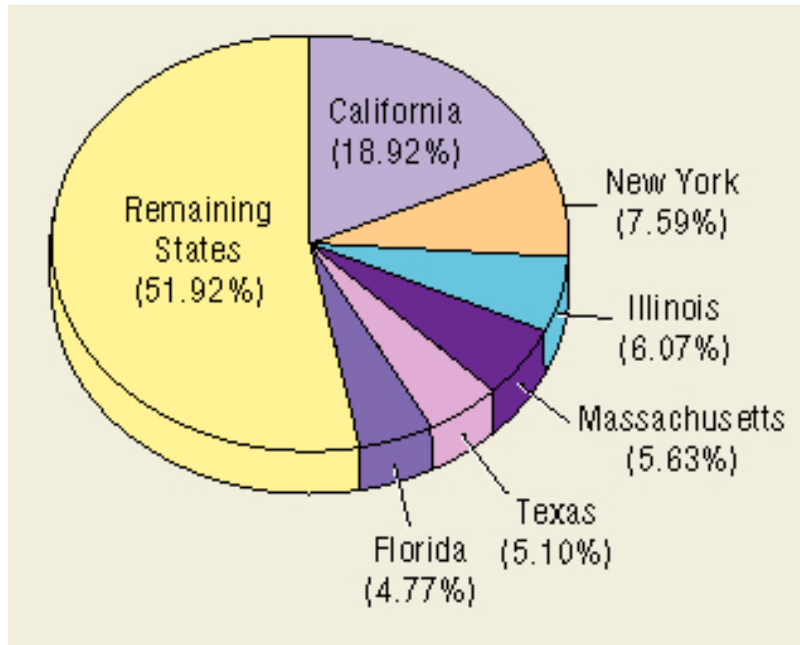
- Orange County Regulatory Affairs Discussion Group
- Volunteer organization
- 501{c}(6) Non-profit organization
- Mission: Education of regulatory professionals and to provide a neutral forum for the exchange of information.
  - Devices - In Vitro Diagnostics
  - Drugs - Biologics
  - Combination Products

# FDA Los Angeles District Serving Southern California & Arizona



\* Excludes Sound Emitting Devices

# California - as compared to the US



- Almost 20% of medical device manufacturers located in CA
- Southern California
  - accounts for 25% of all FDA medical product approvals.
  - Biomedical firms employ over 15,000 residents of Orange County.
  - Home to the largest concentration of medical product manufacturers in the world.
  - Produces more biomedical products and research than anywhere in the world.

\* 1997 data

# 1992

- There was a need for information!
- Only professional meetings were on the East Coast → \$\$\$\$
- Regulatory professionals started seeking each other out.
- Started meeting for “coffee klatch” and lunch discussions.

# 1992 OCRA Founded

- Ed Guilmette,
- Bob Bard
- Steve Lawrence, Hogan & Hartson
- Diana Upp
- Del Stagg, Allergan
- Brian Donato, Hyman, Phelps, & McNamara

# In the beginning

- Meeting notifications sent by US Mail
- No internet, limited access to “reach out”
- No money to fund programs
- No staff. Everyone donated time.
  - Kathy Golas, Hogan & Hartson
- No equipment.

# 1993 - Organized

- Ed Guilmette – 1<sup>st</sup> President
- Created Board of Directors
  - Perianne Di Rocco – Administrator
- Beginning Activities
  - FDA/FDLI Teleconferences – Fullerton College
  - Workshops – at Allergan
  - Organized comments to FDA proposed rules



# FDA Involvement? Yes! Yes! Yes!

- In the beginning
  - Elaine Messa, Los Angeles District Director
  - Jim Kozick, Director of Investigations
  - Tom Sawyer, Compliance Director
  - Mark Roh, current acting Regional Director
- Currently
  - Alonza Cruse, Los Angeles District Director
  - Linda Hartley
  - Katherine Jacobitz
  - Many others participate as speakers

# FDA-OCRA Educational Conference

- 1996 – First Co-sponsored conference
- One day session  
Presented by Hogan & Hartson
- FDA, Hogan & Hartson, and OCRA worked together to obtain industry and FDA speakers
- Goal – current topics in regulatory concerns and compliance issues
- 134 attendees

# FDA Activities

- FDA Open House
- Speakers for OCRA meetings
- Support MDR Network group
- Provide information regarding other conferences and FDA programs in the area.

# Hammer Awards

- Award from Vice-President Al Gore
- Innovative programs for partnership with the US government – better programs/less cost
- Awarded to LA District FDA and OCRA network groups
- 1997: Los Angeles Grassroots Regulatory Partnership
- 1999: MDR Network Group

# OCRA Now - 16 Years Later

- Board of Directors – 11 members
- Program Committee
- Annual Meeting Committee
- Education & Professional Development Committee
- 1 paid Administrator

# Network Groups

- No charge to attend meetings.
- MDR Network Group
- FDA Liaison appointed to support group
- Michael Stokke
- Katherine Jacobitz
- Support from CDRH
- Risk Management Network Group
- Design Control Network Group (DCd)

# OCRA Now

- Over 650 members in 2007; ~100 companies
- 11<sup>th</sup> FDA/OCRA Annual Educational Conference
  - Dr. von Eschenbach – Keynote Speaker
  - Expect over 350 attendees
  - 16 FDA speakers, 14 industry speakers
  - Speakers from Japan MHLW and German Competent Authority
- RAC (Regulatory Affairs Certification) Study Group
- OCRA Newsletter

# OCRA Website

[www.ocra-dg.org](http://www.ocra-dg.org)

- Meeting information
- Job listing
- Links to other regulatory organizations
- Links to area consultants
- Links to other educational programs
- Articles of Incorporation, Mission Statement, and By-Laws



# 2008 Meeting Topics

- Managing Device Modifications
- Inspections 101, Warning Letters, and 483s
- CAPA 101
- Regulatory Document Management, Electronic Filings (STED)
- FDA/OCRA 11<sup>th</sup> Annual Educational Conference
- Tracking and Managing Changes to Standards and Regulations
- Clinical Trials 101 with Lab including IVDs and International
- Doing Business in China
- RAC Exam Study Group (November Exam)
- MDR Network
  - eMDR
  - Complaint Data as Related to CAPA Triggers
  - MDR Case Studies

• Risk Management Network Group – Various topics