
Role of the CDRH Ombudsman

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Ombudsman

Center for Devices and Radiological Health

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Role of CDRH Ombudsman

- **Provide focus to variety of dispute resolution mechanisms**
- **Easing the way to be heard**
- **Accessible to industry;**
 - ▶ **complaints, questions, issues and disputes; suggestions and feedback**
- **Activist, problem-solving Ombudsman**

Role of CDRH Ombudsman (continued)

- **Respond to questions**
- **Advise on options for challenging or appealing decision**
- **Shuttle diplomacy**
- **Mediation**

Role of CDRH Ombudsman (continued)

- Neutral and impartial, facilitate constructive resolution of disputes
- Confidentiality

Initiatives

- **Outreach to industry**
 - ▶ **speaking at trade association meetings**
 - ▶ **meeting with small groups of industry representatives**
 - ▶ **purpose: explain role and listen to issues and concerns**
 - ▶ **MDDI (Medical Device Industry Initiatives Grassroots Task Force). Joint industry/FDA group working together for mutual benefit. Emphasis shifting from field to CDRH-specific issues.**

Initiatives

(continued)

- **In-reach to CDRH staff.**
- **Met with other FDA Ombudsmen**
- **Revising draft Guidance on Resolving Scientific Disputes**

Initiatives

(continued)

- **Impaneling new Medical Devices Dispute Resolution Panel**
 - ▶ **8 members**
 - ▶ **scientific disputes -- no other avenue; performance standards; PMA/PDP; Postmarket Surveillance more than 36 months**
 - ▶ **first meeting tentatively planned for Oct 2000**

Initiatives

(continued)

- **Developing tracking system:
status and statistics**
- **Website**

Full Title

**Ombudsman & Quality Assurance Manager:
two sides of same coin, look at quality and
consistency of decisions; make
recommendations for improvement.**

US Ombudsman Association Mission

**To promote and support fairness,
accountability, and equity in government.**

How to Contact the CDRH Ombudsman:

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