



# DALLAS DISTRICT FDA / MEDICAL DEVICE INDUSTRY COALITION

## CHARTER

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### **HISTORICAL PERSPECTIVE:**

The Dallas District FDA/Industry Medical Device Coalition was formed during a meeting of officials from FDA Dallas District, Texas Department of Health and industry association representatives in April 1997 in Dallas, Texas. The Coalition was established to continue the efforts of the 1995/1996 Device Grassroots Meetings held between FDA and industry which occurred to facilitate effective interaction between the device industry and FDA's district field offices.

### **MISSION:**

To facilitate the availability of safe and effective medical devices through enhanced communications and cooperation between industry, appropriate state agencies, and the FDA.

### **ORGANIZATIONAL PURPOSE:**

- 1) To identify, address and obtain feedback on issues of concern.
- 2) To disseminate information on activities of the Coalition through appropriate means.
- 3) To improve/increase technical knowledge of products, processes and regulations.

### **ORGANIZATIONAL STRUCTURE:**

The Coalition is an independent, non-profit organization composed of individuals from the device industry, state and federal government representatives and representatives from academia. The names of eight to ten industry representatives, from within Dallas District, will be submitted to FDA by medical device associations for consideration. Nominees recommended for membership will be submitted on association letterhead to the Coalition co-chairs. The Coalition will, subsequently, vote on submitted membership proposals. The selected individuals will represent various segments of the device industry associations including type and size.

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Government representatives may include managers from Texas Department of State Health Services, representatives from the Dallas District Office (the medical device program manager, senior medical device investigators and district managers) and representatives from the Southwest Regional Office (small business representative and regional management). The coalition may also include representatives(s) from academia.

There are no fees or membership dues collected from the members of the coalition.

### **ELECTION OF OFFICERS:**

The Coalition will elect two individuals from the current membership to serve as co-chairs for one, two-year term. Co-chairs will not serve successive terms. One co-chair will be selected from association members and one co-chair will be selected from government members.

### **MEETINGS:**

The Coalition will formally meet quarterly for one day at an agreed upon site. Designated members are expected to attend or to send an alternate in order to maintain active status.

### **ETHICS:**

Individual members will refrain from performing any action, during a coalition sponsored activity, from which they will derive private gain e.g. solicitation of services.

Version	Description of Change	Regulatory Co-Chair	Industry/Academia Co-Chair	Quality Committee Chair
9 Oct 09	Reformatted in entirety from the document adopted September 15, 2000; added change control section			