FMDIC, INC.

History

The US Food and Drug Administration (FDA) - Medical Device Industry Coalition, FMDIC, INC. (FMDIC) was formed to facilitate effective interaction between the device industry and FDA's district field offices. FMDIC was incorporated in the State of Texas in August 14, 2012.

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:

FMDIC 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 industry representatives, from within Dallas District, were submitted to FDA by medical device associations for consideration. Nominees recommended for membership were submitted on association letterhead to the FMDIC co-chairs. FMDIC votes on submitted membership proposals. The selected individuals represent various segments of the device industry associations including type and size.

Government representatives include managers from Texas Department of State Health Services, representatives from the FDA Dallas District Office (the medical device program manager, senior medical device investigators and district managers) and representatives from the Southwest Regional Office. FMDIC may also include representatives(s) from academia.

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

FMDIC meets quarterly to perform its purpose and minutes are taken.

EVENTS:

In order to fulfill its mission and purpose FMDIC holds events with FDA and industry experts as presenters to educate the medical device industry in the various elements of the Quality System Regulation and also provides smaller venues for a one-day general seminar of the FDA regulations for the medical device industry. Fees are charged to pay for the expenses and to provide for future events. Funds are also used to provide grants to universities for deserving university students in the medical device field chosen by the individual institutions.