FDA SUCCESS STORIES

The FDA Center for Devices and Radiological Health (CDRH)worked with the American National Standards Institute and the International Organization of Standards to develop a standard for contact lens products that reduced agency review time, among many other results. Contact: Dave Whipple

The FDA's award winning, premier broadcast teleconferencing center was born in part from the marriage of the agency's studio and an ad hoc network of downlink sites sponsored by groups who partnered with the agency. Contact: Robert McCleary

The May '98 live interactive educational International Latex Allergy teleconference was a collaboration between 17 major Federal and non-Federal stakeholder organizations who contributed funding and other support for possibly the largest audience of health care professionals ever. Contact: Sharon Dillard

FDA's Center for Food Safety and Applied Nutrition with the support of industry trade groups in the early 1980's launched a program of industry education that continues today. Contact: Cynthia Leggett

The FDA ensures national standards for mammography quality via a State Working Group that assists CDRH in developing Demonstration Projects and a Regulatory Program. Contact: Ruth Fischer

CDRH and a number of volunteer firms are piloting in the medical device industry use of a system of controls used in other industries to produce safe and effective products. This should result in more efficient inspections and possibly also product approvals. Contact: Adrianne Galdi

The FDA Center for Drugs is piloting a program where firms would provide quality assurance information to FDA and consequently undergo modified FDA inspections-- a First Party Audit Program. Contact: Russ Rutledge

In an effort to resolve outstanding issues with refurbishers of medical devices (products that are not subejct to the usual level of premarket and postmarket regulatory oversight by FDA), CDRH and the affected industry met in public forums to find points of common understanding. Contact: Cap Uldriks

The bio-statisticians in CDRH must weigh in on all pre-market applications by device manufacturers. Outreach programs and guidance developed with the firms involved should improve submissions and reduce the impact on the statisticians' resources. Contact: Greg Campbell

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The FDA Center for Devices and Radiological Health (CDRH)worked with the American National Standards Institute and the International Organization of Standards to develop a standard for contact lens products that reduced agency review time, among many other results. Contact: Dave Whipple

The FDA's award winning, premier broadcast teleconferencing center has successfully used and ad hoc network of downlink sites sponsored by and paid for groups who partnered with the agency to deliver important public health messages to diverse audiences. Contact: Robert McCleary

The May '98 live, interactive, educational teleconference, *Natural Rubber Latex Allergy Recognition, Treatment and Prevention,* was a collaboration between 17 major Federal and non-Federal stakeholder organizations who contributed funding and other support. This award-winning international telecast was thought to have reached the largest audience of health care professionals ever via satellite downlink and included provision for continuing education credits. Contact: Sharon Dillard

FDA's Center for Food Safety and Applied Nutrition (CFSAN) with the support of industry trade groups in the early 1980's launched a program of industry sponsored / FDA endorsed education that continues today. Contact: Cynthia Leggett

The FDA ensures national quality standards for mammography via a State Working Group that assists CDRH in developing Demonstration Projects and a regulatory program. Contact: Ruth Fischer

CDRH and a number of volunteer firms in the medical device industry are piloting a system of hazard analysis and process controls used in other industries to produce safe and effective products. This should result in more efficient FDA inspections and possibly also faster product approvals. Contact: Adrianne Galdi

The FDA Center for Drug Evaluation and Research (CDER) is piloting a program where firms would provide quality assurance information to FDA and consequently undergo modified FDA inspections-- a First Party Audit Program. Contact: Russ Rutledge

In an effort to resolve outstanding issues with refurbishers of medical devices (products that are not subejct to the usual level of pre-market and postmarket regulatory oversight by FDA), CDRH and the affected industry met in public forums to find points of common understanding and begin a "problem solving dialogue." Contact: Cap Uldriks

The bio-statisticians in CDRH must weigh in on all pre-market applications by device manufacturers. Outreach programs and guidance developed to improve the use of statistics in the firms' proposals should improve submissions and reduce statistician workloads later in the review process. Contact: Greg Campbell