

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

U.S. Food and Drug Administration - Center for Devices and Radiological Health

Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices

5/1/95 (G95-1)

Popular Items

Interacting w/CDRH

Special Interest

Premarket

Postmarket

Rad. Health

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NOTE: This memo was distributed with Blue Book Memorandum #G95-1, entitled Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" and relates to implementation of #G95-1.

May 1, 1995

Director, Office of Device Evaluation (ODE)

Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices

Division Directors, ODE

The new blue book memorandum #G95-1 entitled "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing," includes an FDA-modified matrix that designates the type of testing needed for various medical devices (copy attached). It also includes a flow chart entitled "Biocompatibility Flow Chart for the Selection of Toxicity Tests for 510(k)s." The guidance will be effective for all submissions that will be received on or after July 1, 1995. The former guidance, #G87-1 entitled "Tripartite Biocompatibility Guidance," may continue to be applied until a final decision is reached on each submission received

Vintage Documents from Clinical Device Group

Is this the document you are looking for? Just email us [here](#) to obtain the entire copy of the FDA May 1995 Blue Book Memo G95-1 "Required Biocompatibility Training and Toxicology Profile for Evaluation of Medical Devices," free and with our compliments.

Best regards,
Nancy J Stark, PhD
President, Clinical Device Group Inc

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