Medical Devices Current Good Manufacturing Practice Quality System Regulation

0910-0073

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting extension of approval for information collection requirements in 21 CFR Part 820. http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=afcb5c61a16e62e65ebb7539ad68aeea&tpl=/ecfrbrowse/Title21/21cfr820_main_02.tpl

Current Good Manufacturing Practices (CGMPs) are set forth in the Quality System (QS) regulation. The authority for this regulation is covered under the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, and 383).

The CGMP/QS regulation includes requirements for purchasing and service controls; clarifies recordkeeping requirements for device failure and complaint investigations; clarifies requirements for verifying/validating production processes and process or product changes; and clarifies requirements for product acceptance activities, quality data evaluations, and corrections of nonconforming product/quality problems. Requirements are compatible with specifications in international quality standards, ISO 9001, "Quality Systems Model for Quality Assurance in Design/ Development, Production, Installation, and Servicing." See American National Standard ANSI/ASQC Q 9001-1994, which corresponds to ISO 9001:1994. Harmonization is fostered by the Safe Medical Devices Act of 1990 (SMDA) section 15, which added section 803 to the FD&C Act to encourage FDA to establish an Office of International Relations to work with foreign countries towards mutual recognition of CGMP requirements.

Below is a description of information collection requirements in the CGMP/QS regulation:

Quality policy—21 CFR 820.20(a)—*Recordkeeping*
Executive management shall establish (i.e. define, document, implement) the quality policy and maintain it at all organizational levels.

Organization—21 CFR 820.20(b)—*Recordkeeping*
Manufacturers shall establish and maintain organizational structure adequate to design and produce devices, and establish responsibilities and resources appropriate to manage, perform, and assess activities affecting quality.

Management review—21 CFR 820.20(c)—*Recordkeeping*
Quality systems shall be reviewed for suitability and effectiveness at defined intervals; and dates and results, documented.

Quality planning—21 CFR 820.20(d)—*Recordkeeping*
A quality plan defining quality practices, resources, and activities, shall be established and maintained.

Quality system procedures—21 CFR 820.20(e)—*Recordkeeping*
Manufacturers shall establish and maintain quality system procedures, instructions; and outline appropriate documentation.

Quality audit—21 CFR 820.22—*Recordkeeping*
Quality system audits/reaudits shall be done per established procedures; and results and dates, documented in reports reviewed by management.

Training—21 CFR 820.25(b)—*Recordkeeping*
Manufacturers shall establish and maintain procedures identifying training needs, and document training.

Design procedures—21 CFR 820.30(a)(1)—*Recordkeeping*
Manufacturers of Class III, II and certain Class I devices shall establish and maintain procedures for the design of devices.

Design and development planning—21 CFR 820.30(b)—*Recordkeeping*
A plan describing design and development activities shall be established, maintained, reviewed, updated and approved as device design evolves.

Design input—21 CFR 820.30(c)—*Recordkeeping*
Procedures identifying design input requirements shall be established and maintained; and requirements, approval dates and persons, documented.

Design output—21 CFR 820.30(d)—*Recordkeeping*
Procedures defining design output and acceptance criteria shall be established and maintained; and approvals of design output records, documented.

Design review—21 CFR 820.30(e)—*Recordkeeping*
Procedures shall be established and maintained for systematic design review; and results, documented in the design history file (DHF).

Design verification—21 CFR 820.30(f)—*Recordkeeping*
Procedures shall be established and maintained for verifying device design; and, results, dates, methods and persons used, documented in the DHF.

Design validation—21 CFR 820.30(g)—*Recordkeeping*
Procedures shall be established and maintained for validating design; and results, dates, methods and persons, documented in the DHF.

Design transfer—21 CFR 820.30(h)—*Recordkeeping*
Procedures shall be established and maintained ensuring the device design is correctly translated into production specifications.

Design changes—21 CFR 820.30(i)—*Recordkeeping*
Procedures shall be established and maintained to identify, document, verify or validate, review and approve design changes, before implementation.

Design history file—21 CFR 820.30(j)—*Recordkeeping*
A DHF shall be established/maintained for each device, referencing records showing the device was developed per the design plan/requirements.

Document controls—21 CFR 820.40—*Recordkeeping*
Manufacturers shall establish and maintain procedures controlling approval and distribution of required documents and document changes.

Documentation approval and distribution—21 CFR 820.40(a)—*Recordkeeping*
Before issuance, all documentation shall be reviewed and approved by designated personnel; and, approval dates and signatures, documented.

Document changes—21 CFR 820.40(b)—*Recordkeeping*
Manufacturers shall maintain a record of approved changes, including descriptions, affected documents, approval dates, and signatures.

Purchasing controls—21 CFR 820.50(a)—*Recordkeeping*
Manufacturers shall establish/maintain procedures for product quality requirements to be met by suppliers, contractors; record evaluations; define controls based on these evaluations; and, maintain a record of acceptable suppliers.

Purchasing data—21 CFR 820.50(b)—*Recordkeeping*
Purchasing documents identifying specified requirements for products and services, shall be established, reviewed and approved.

Identification—21 CFR 820.60—*Recordkeeping*
Procedures shall be established and maintained for identifying product during receipt, production, distribution and installation.

Traceability—21 CFR 820.65—*Recordkeeping*
Procedures shall be established and maintained to identify, by control number, lots of life supporting or sustaining implants and their components.

Production and process controls—21 CFR 820.70(a)—*Recordkeeping*
Manufacturers shall establish and maintain process control procedures, including instructions, SOPs, production methods, monitoring measures for parameters, reference standards, approvals, and workmanship criteria.

Production and process changes—21 CFR 820.70(b)—*Recordkeeping*
Procedures shall be established and maintained for changes in a specification, method, process, or procedure, including verification or validation.

Environmental control—21 CFR 820.70(c)—*Recordkeeping*
Manufacturers shall establish and maintain procedures to control environmental conditions and document results of systems inspections.

Personnel—21 CFR 820.70(d)—*Recordkeeping*
Requirements shall be established and maintained for personnel's health, cleanliness, practices and clothing adversely affecting product quality.

Contamination control—21 CFR 820.70(e)—*Recordkeeping*
Each manufacturer shall establish and maintain procedures to prevent equipment and product contamination by adverse substances.

Equipment maintenance schedule—21 CFR 820.70(g)(1)—*Recordkeeping*
Schedules shall be established and maintained for equipment adjustment, cleaning and maintenance; and maintenance, documented.

Equipment maintenance inspection—21 CFR 820.70(g)(2)—*Recordkeeping*
Results of periodic maintenance inspections, dates, and inspectors shall be documented.

Adjustment—21 CFR 820.70(g)(3)—*Recordkeeping*
Limitations or tolerances shall be posted on or near equipment and be available to adjusters.

Manufacturing material—21 CFR 820.70(h)—*Recordkeeping*
Manufacturers shall establish and maintain procedures for using and removing adverse manufacturing materials.

Automated processes—21 CFR 820.70(i)—*Recordkeeping*
A protocol shall be established to validate software/changes for computers and automatic data processing; and validation results, documented.

Control of inspection, measuring, and test equipment—21 CFR 820.72(a)—*Recordkeeping*
Procedures shall be established/maintained for equipment calibration, inspection, checks, handling, storage and for documenting these activities.

Calibration procedures—21 CFR 820.72(b)—*Recordkeeping*
Established calibration procedures shall provide for directions, accuracy/precision limits, and remedial actions; and such actions, documented.

Calibration standards—21 CFR 820.72(b)(1)—*Recordkeeping*
Absent national or international calibration standards, manufacturers shall establish and maintain in-house standards.

Calibration records—21 CFR 820.72(b)(2)—*Recordkeeping*
Records shall identify calibrated equipment, dates, calibrators and next calibration.

Process validation—21 CFR 820.75(a)—*Recordkeeping*
Validation procedures shall be established and maintained for processes whose results are not verifiable by inspection and test; and validation results, dates, approving signatures and equipment, documented.

Validated process parameters—21 CFR 820.75(b)—*Recordkeeping*
Procedures shall be established and maintained for keeping validated process parameters within specified parameters.

Validated process monitoring, control methods, and data—21 CFR 820.75(b)(2)—*Recordkeeping*
Monitoring, control methods, and data for validated processes shall be documented.

Revalidation—21 CFR 820.75(c)—*Recordkeeping*
Results of revalidation activities for product changes or process deviations shall be documented.

Acceptance activities procedures—21 CFR 820.80(a)—*Recordkeeping*
Manufacturers shall establish and maintain procedures for acceptance activities, including inspections, tests or other assessments.

Receiving acceptance activities—21 CFR 820.80(b)—*Recordkeeping*
Procedures shall be established/maintained for incoming acceptance by inspection/test/other verification; and acceptance/rejection, documented.

In-process acceptance activities—21 CFR 820.80(c)—*Recordkeeping*
Procedures shall be established and maintained to ensure in-process product meets specified requirements and is controlled until inspections, tests or verifications are completed and approvals, documented.

Final acceptance activities—21 CFR 820.80(d)—*Recordkeeping*
Procedures shall be established and maintained so that finished devices meet acceptance criteria and are not distributed until device master record (DMR) activities are completed; data, reviewed; and approvals, documented.

Acceptance records—21 CFR 820.80(e)—*Recordkeeping*
Acceptance dates, results, performance signatures and equipment shall be recorded in the device history record (DHR).

Acceptance status—21 CFR 820.86—*Recordkeeping*
Product acceptance status shall be identified during receipt, manufacture, packaging, labeling, installation and servicing.

Control of nonconforming product—21 CFR 820.90(a)—*Recordkeeping*
Manufacturers shall establish and maintain procedures for identification, documentation, evaluation, and disposition of nonconforming product.

Nonconforming product review/disposition procedures—21 CFR 820.90(b)(1)—*Recordkeeping*
Manufacturers shall establish/maintain procedures for review/disposition of nonconforming product; and dispositions/concessions, documented.

Rework procedures—21 CFR 820.90(b)(2)—*Recordkeeping*
Procedures shall be established/maintained for rework, reevaluation of product/adverse rework effects; and, activities/results, recorded in DHR.

Procedures for corrective/preventive actions—21 CFR 820.100(a)(1-7)—*Recordkeeping*
Procedures and requirements shall be established and maintained for corrective/preventive actions, including: analysis of data from process, work, quality, servicing records; investigation of nonconformance causes; identification of corrections and their effectiveness; recording of changes made; and, appropriate distribution and managerial review of corrective and preventive action information.

Corrective/preventive activities—21 CFR 820.100(b)—*Recordkeeping*
All corrective/preventive activities shall be documented.

Labeling procedures—21 CFR 820.120—*Recordkeeping*
Manufacturers shall establish/maintain procedures to control labeling storage/application; and examination/release for storage and use, documented.

Labeling documentation—21 CFR 820.120(b) and (d)—*Recordkeeping*
Labels/labeling used shall be documented in DHR.

Device packaging—21 CFR 820.130—*Recordkeeping*
Manufacturers shall ensure device packaging and shipping containers are designed to protect devices from alteration or damage.

Handling—21 CFR 820.140—*Recordkeeping*
Handling procedures shall be established and maintained to prevent product mix-ups and adverse effects.

Storage—21 CFR 820.150(a) and (b)—*Recordkeeping*
Manufacturers shall establish/maintain procedures for controlling product storage areas/stock rooms and for authorizing receipt/dispatch.

Distribution procedures—21 CFR 820.160(a)—*Recordkeeping*
Manufacturers shall establish/maintain distribution control procedures so released devices- distributed, errors- resolved, expired product- not distributed.

Distribution records—21 CFR 820.160(b)—*Recordkeeping*
Distribution records shall be maintained, identifying consignees, products, quantities, dates, and control numbers shipped.

Installation—21 CFR 820.170—*Recordkeeping*
For installed devices, manufacturers shall establish instructions, inspection/test procedures, make them available, and record results.

Record retention period—21 CFR 820.180(b) and (c)—*Recordkeeping*
Required records shall be: maintained at manufacturing sites or other sites accessible to manufacturers and FDA; made readily available to FDA; retained for device's life expectancy or 2 years; and, per request, audit reviews certified.

Device master record—21 CFR 820.181—*Recordkeeping*
Manufacturers shall maintain DMRs that contain reference: device/process specifications, quality assurance procedures/specifications, packaging /labeling specifications, and installation/maintenance/servicing procedures.

Device history record—21 CFR 820.184—*Recordkeeping*
For each unit/lot/batch, manufacturers shall maintain DHRs demonstrating manufacture per DMR/regulatory requirements; manufacturing dates; quantities made/distributed; acceptance records; labels/labeling; control numbers.

Quality system record—21 CFR 820.186—*Recordkeeping*
Manufacturers shall maintain a quality system record (QSR) that contains/references/documents procedures/activities not specific to particular devices.

Complaint files—21 CFR 820.198(a), (c), and (g)—*Recordkeeping*
Manufacturers shall maintain complaint files/establish procedures for receiving/reviewing/evaluating complaints, to include: recording why complaints are not investigated, and investigating complaints about devices not meeting specifications or associated with events reportable to FDA under separate regulations; and, when

complaint units are at separate or foreign sites, maintaining the records at the manufacturer's regular U.S. records site, or at the firm's U.S. designated agent.

Servicing procedures—21 CFR 820.200(a)—*Recordkeeping*
Where servicing is required, manufacturers shall establish/ maintain procedures for performing/verifying that servicing requirements are met and service reports (for FDA reportable events) are processed as complaints.

Service reports—21 CFR 820.200(d)—*Recordkeeping*
Service reports shall record the device, date, service, service done, and test and inspection data.

Statistical techniques procedures—21 CFR 820.250(a)—*Recordkeeping*
As appropriate, manufacturers shall establish and maintain procedures to identify valid statistical techniques to access process/product acceptability.

Sampling plans—21 CFR 820.250(b)—*Recordkeeping*
Written sampling plans shall be based on valid statistical rationale; and procedures, established, maintained and reviewed to ensure their adequacy.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

The respondents to this information are private sector, for-profit businesses.

CGMP/QS information collections assist FDA inspections of manufacturer compliance with quality system requirements encompassing design, production, installation, and servicing processes. Manufacturers must ensure that medical devices meet design specifications and that design specifications are effectively transferred from research and development to production. Manufacturer compliance with CGMP/QS requirements should decrease such failures and save manufacturers millions of dollars by avoiding recalls caused by inadequate design.

“Harmonized” CGMP/QS requirements have benefited export-oriented manufacturers because they are consistent with the ISO 9000 international quality standards. The least expensive way for U.S. firms to meet the medical device directives of the European Union (EU) and obtain the EU mark to sell their products is to certify that their quality systems comply with the ISO standards. By complying with CGMP/QS requirements U.S. manufacturers will satisfy both domestic and international regulatory requirements.

Not implementing the CGMP/QS regulation would result in the continuation of a significant number of preventable deaths and injuries, and in the loss by manufacturers of substantial savings attributable to reduced recall costs, improved manufacturing efficiency, and improved access to international markets.

3. Use of Improved Information Technology and Burden Reduction

FDA estimates that approximately 75% of the respondents will use electronic means to fulfill the agency's requirement or request.

In the Federal Register of March 20, 1997 (62 FR 13430), FDA published a final rule establishing procedures for electronic records, electronic signatures, and electronic submissions. Firms may use appropriate technology in accordance with this rule to comply with the CGMP/QS recordkeeping requirements.

FDA is also using information technology to assist in the reduction of information burden to respondents of information queries. Presently, respondents to FDA information collections may use computer word processing, electronic form, spreadsheet, and database software to collect and format information.

FDA has attempted to maximize current technology to reduce burden for respondents of its data by the methods mentioned above. FDA will continue to pursue methods of applying technology to reduce burden to the respondents of its information collections.

4. Efforts to Identify Duplication and Use of Similar Information

Required information is available from individual manufacturers and no other sources. FDA is the only Federal regulatory agency responsible for collecting such information.

5. Impact on Small Businesses or Other Small Entities

Under the Small Business Administration's definition of a small business, 98% of the manufacturers who keep records are small businesses.

CGMP/QS requirements have a significant impact on a substantial number of small businesses. However, when the CGMP/QS became final rule and exempted the majority of Class I device manufacturers from design controls, FDA estimated a decrease in compliance costs by approximately $6.8 million, 60 percent of which would have been borne by small businesses. By excluding component manufacturers from CGMP/QS requirements, FDA eliminated potential rises in the cost of components purchased by small businesses. By deleting "complete" and "all" from many previous recordkeeping provisions, FDA provides small businesses with greater flexibility in determining the type and quantity of necessary records. By harmonizing requirements with international standards, FDA provides benefits to small firms pursuing exports since they no longer need to expend resources to maintain a quality system for FDA regulated domestic products and another for foreign regulated exports.

Small firms are assisted by the Division of Small Manufacturers Assistance (DSMICA) within FDA's Center for Devices and Radiological Health (CDRH). DSMICA was established, as required by the 1976 Amendments to the FD&C Act, to provide technical and other non-financial assistance to small firms, expressly to aid them in complying with the requirements of the FD&C Act. DSMICA participates in and conducts conferences, workshops, and seminars on the application and interpretation of relevant regulations.

DSMICA also consults with small firms, and develops and disseminates CGMP educational materials, thereby reducing small business expenditures to achieve compliance. DSMICA staff are available to respond to questions via a toll-free telephone number, and they provide additional information to firms on the DSMICA website, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

6. Consequences of Collecting the Information Less Frequently

There are no technical or legal obstacles to the collection of information required by this collection. Respondents keep records on a daily basis.

Section 510(h) of the FD&C Act requires FDA to inspect registered manufacturers of Class II (special controls) devices and Class III (premarket approval) devices, at least once every 2 years. FDA inspects manufacturers of Class I (general controls) devices as often as feasible. If inspection reviews were conducted less frequently, FDA's effectiveness in increasing the safety of medical devices by monitoring manufacturers' compliance with CGMPs, would be significantly reduced.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Collections are consistent with 5 CFR 1320.5 except for the requirement in section 820.180(b). This section requires records to be retained for a period equivalent to the design and expected life of the device, but in no case less than 2 years from release for distribution. This is necessary because many devices are labeled for extended periods of use. For example, pacemaker life expectancy depends on battery life, which is usually more than 3 years. Manufacturers must retain records as required above in order to perform failure/problem investigations and FDA must have access to these records to conduct long range investigations protecting public health.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of 07/31/2013 (78 FR 46347). We received one comment.

The comment agreed that the information has practical utility, but requested clarification regarding whether records gathered in electronic format will be made available outside of FDA.

Disclosure of QS records is governed by the Freedom of Information Act (5 U.S.C. 552) and FDA's Public Information regulation at 21 CFR part 20. Section 820.180(a) of the CGMP/QS regulation provides that records deemed confidential by manufacturers may be marked to aid FDA in determining what information may be disclosed under 21 CFR part 20. This applies to both paper and electronic QS records.

Another part of the comment expressed a belief that "the burden on industry of complying with FDA requests for information during an inspection is based on data FDA maintains on actual inspections; the estimates are averages" and that "it is unclear how

FDA arrived at these estimates since they seem high when spread out across all registered device manufacturers."

The comment assumes that the burden estimate includes only the burden of responding to information requests during an inspection. However, the estimates also include the burden of collecting, maintaining, and retaining the records. The comment's suggestion of 3.5 hours per year for "responding to information requests during an inspection" does not appear to include the burden of collecting, maintaining, and retaining the records and is based on the experience of only one segment of industry. Except for manufacturers, not every type of firm is subject to every CGMP/QS requirement. For example, all are subject to Quality Policy (§820.20(a)), Document Control (§820.40), and other requirements, whereas only manufacturers and specification developers are subject to subpart C, Design Controls. The estimated burden is, therefore, an average burden.

As a basis for its burden estimates, the agency relied in part on certain information found in a study originally developed under FDA contract by Eastern Research Group, Inc. (ERG) when the CGMP/QS regulation became final. The study was submitted to OMB as part of the original PRA approval and is part of the federal docket. The agency performs ongoing reviews of the information collection burden as required under the PRA for purposes of evaluating burden associated with its information collection requests, and has done so for the purpose of extending the recordkeeping requirements associated with the CGMP/QS regulations. The commenter believes that the estimates the agency provides are too high. However, the commenter does not offer an alternative methodology for estimating that the agency may review. For these reasons we have not changed the hourly burden estimate.

The comment also suggests that FDA did not make clear what was meant by the "quality, utility and clarity of the collected information" in the 60-day notice requesting public comment on the information collection. "Quality, utility and clarity" have the same meaning as in OMB's regulations at 5 CFR 1320.8(d)(1)(iii).

Another part of the comment addressed concerns about the use of electronic means to fulfill the information collection requirements. The comment seems to assume that it would take additional time to provide electronic records at the request of an inspector because records that are not kept in electronic format would need to be scanned in order to fulfill the inspector's request. The comment also requests that FDA "publish procedures for the use of any electronic submissions which may be contemplated" to help the commenter allay concerns about misuse of photographs and electronic submissions.

At this time, fulfillment of the information collection via electronic means is optional. We estimate that approximately 75 percent of respondents currently use some form of electronic recordkeeping to fulfill the information collection. Firms may use appropriate technology in accordance with FDA's "Electronic Records; Electronic Signatures" final rule (62 FR 13430, March 20, 1997) to comply with the CGMP/QS recordkeeping requirements. However, respondents may make the records available in paper format.

There is no additional requirement that respondents convert existing paper records to an electronic format.

The comment also requests an explanation regarding the citation of the standard "ISO 9001" in the 60-day notice for public comment, rather than "ISO 13485."

In the notice, we included background information regarding the Quality System Regulation (21 CFR part 820). We referenced "ISO 9001: Quality Systems Model for Quality Assurance in Design/Development, Production, Installation, and Servicing" because at the time the Quality System Regulation was issued and the preamble was written, ISO 9001 was the current standard.

Additionally, the comment requests clarification regarding the Agency's contemplation of new submissions of information and includes suggestions related to such new submissions.

At this time, there is no new requirement for submission of information under the QS regulations. Any future new requirements for information collection will be made available for public comment as required by 5 CFR part 1320.

CDRH is proactive in ensuring that the medical device industry and other affected individuals are made aware of ongoing issues relating to the CGMP/QS regulations. The FDA's Medical Device GMP/QS experts have participated in numerous conferences and seminars relating to the CGMP/QS regulatory requirements. During these sessions, our GMP/QS experts share information through speeches and panel discussions that provide a forum for open discussion. During these discussions guidance and direction is often given to the audience to help them understand their regulatory responsibilities under the GMP/QS regulation. In addition, issues are sometimes identified by the audience that provides the Agency areas that we may need to clarify to affected individuals.

9. Explanation of Any Payment or Gift to Respondents

There is no payment or gift to respondents of this information collection.

10. Assurance of Confidentiality Provided to Respondents

CDRH complies with the Freedom of Information Act (5 U.S.C. 552) and FDA's Public Information regulation at 21 CFR part 20. Section 820.180(a) of the CGMP/QS regulation provides that records deemed confidential by manufacturers may be marked to aid FDA in determining what information may be disclosed under 21 CFR part 20.

11. Justification for Sensitive Questions

This information collection does not include questions that are of a sensitive nature, such as, sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates the burden for this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden					
Activity/ 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Quality policy--820.20(a)	25,986	1	25,986	7	181,902
Organization--820.20(b)	25,986	1	25,986	4	103,944
Management review--820.20(c)	25,986	1	25,986	6	155,916
Quality planning--820.20(d)	25,986	1	25,986	10	259,860
Quality system procedures--820.20(e)	25,986	1	25,986	10	259,860
Quality audit--820.22	25,986	1	25,986	33	857,538
Training--820.25(b)	25,986	1	25,986	13	337,818
Design procedures--820.30(a)(1)	25,986	1	25,986	2	51,972
Design and development planning--820.30(b)	25,986	1	25,986	6	155,916
Design input--820.30(c)	25,986	1	25,986	2	51,972
Design output--820.30(d)	25,986	1	25,986	2	51,972
Design review--820.30(e)	25,986	1	25,986	23	597,678
Design verification--820.30(f)	25,986	1	25,986	37	961,482
Design validation--820.30(g)	25,986	1	25,986	37	961,482
Design transfer--820.30(h)	25,986	1	25,986	3	77,958
Design changes--820.30(i)	25,986	1	25,986	17	441,762
Design history file--820.30(j)	25,986	1	25,986	3	77,958
Document controls--820.40	25,986	1	25,986	9	233,874
Documentation approval and distribution and document changes--820.40(a) and (b)	25,986	1	25,986	2	51,972
Purchasing controls--820.50(a)	25,986	1	25,986	22	571,692
Purchasing data--820.50(b)	25,986	1	25,986	6	155,916
Identification--820.60	25,986	1	25,986	1	25,986
Traceability--820.65	25,986	1	25,986	1	25,986
Production and process controls--820.70(a)	25,986	1	25,986	2	51,972
Production and process changes and environmental control--820.70(b) and (c)	25,986	1	25,986	2	51,972
Personnel--820.70(d)	25,986	1	25,986	3	77,958
Contamination control--820.70(e)	25,986	1	25,986	2	51,972
Equipment maintenance schedule, inspection, and adjustment--820.70(g)(1)-(g)(3)	25,986	1	25,986	1	25,986
Manufacturing material--820.70(h)	25,986	1	25,986	2	51,972
Automated processes--820.70(i)	25,986	1	25,986	8	207,888
Control of inspection, measuring, and test equipment--820.72(a)	25,986	1	25,986	5	129,930
Calibration procedures, standards, and records--820.72(b)(1)-(b)(2)	25,986	1	25,986	1	25,986
Process validation--820.75(a)	25,986	1	25,986	3	77,958
Validated process parameters, monitoring, control methods, and data--	25,986	1	25,986	1	25,986

Table 1.--Estimated Annual Recordkeeping Burden					
Activity/ 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
820.75(b)					
Revalidation--820.75(c)	25,986	1	25,986	1	25,986
Acceptance activities--820.80(a)-(e)	25,986	1	25,986	5	129,930
Acceptance status--820.86	25,986	1	25,986	1	25,986
Control of nonconforming product--820.90(a)	25,986	1	25,986	5	129,930
Nonconforming product review/disposition procedures and rework procedures--820.90(b)(1)-(b)(2)	25,986	1	25,986	5	129,930
Procedures for corrective/preventive actions--820.100(a)(1)-(a)(7)	25,986	1	25,986	12	311,832
Corrective/preventive activities--820.100(b)	25,986	1	25,986	1	25,986
Labeling procedures--820.120(b)	25,986	1	25,986	1	25,986
Labeling documentation--820.120(d)	25,986	1	25,986	1	25,986
Device packaging--820.130	25,986	1	25,986	1	25,986
Handling--820.140	25,986	1	25,986	6	155,916
Storage--820.150(a) and (b)	25,986	1	25,986	6	155,916
Distribution procedures and records--820.160(a) and (b)	25,986	1	25,986	1	25,986
Installation--820.170	25,986	1	25,986	2	51,972
Record retention period--820.180(b) and (c)	25,986	1	25,986	2	51,972
Device master record--820.181	25,986	1	25,986	1	25,986
Device history record--820.184	25,986	1	25,986	1	25,986
Quality system record--820.186	25,986	1	25,986	1	25,986
Complaint files--820.198(a), (c), and (g)	25,986	1	25,986	5	129,930
Servicing procedures and reports--820.200(a) and (d)	25,986	1	25,986	3	77,958
Statistical techniques procedures and sampling plans--820.250	25,986	1	25,986	1	25,986
Totals					9,043,128

All registered establishment types must comply with the CGMP/QS regulations. Upon review of the data and this ICR under the PRA we have also determined that, for accuracy, it is preferable to estimate the number of respondents based on the number of establishments, rather than the number of owner/operators of those establishments. A query of the Agency's registration and listing databank for fiscal year (FY) 2012 shows that 15,113 domestic and 10,873 foreign establishments are subject to the regulations. Therefore, approximately 25,986 respondents must comply with the CGMP/QS regulations. Because the total number of registered establishments is not static, the number of respondents will fluctuate from year to year resulting in changes to the overall burden.

12b. Annualized Cost Burden Estimate

FDA estimates the annualized cost burden as $294,376,429. Upon review of the information collection, we have determined, based on Agency data and expertise, that recordkeeping is performed by several types of worker. We used the occupational categories and updated wage rates from the Bureau of Labor and Statistics data, "NAICS 541000 Professional, Scientific & Technical Services" series, http://www.bls.gov/iag/tgs/iag54.htm to update the cost burden estimate. The increase of the estimated annual burden hours (see explanation in section 15 of this supporting statement) and the updated wage rates (which increased by approximately 95%, using the 2013 average wage rate for type of respondents below, $33.32) have resulted in an increase of $241,279,701 to the estimated annual cost burden.

The total cost burden recorded in ICRAS appears not to have been updated upon extension of this ICR in 2010. As a result, the burden, which appears currently in ICRAS and which is listed in the Notice of Approval, $1,200,000, is incorrect. The supporting statement for the 2010 extension of the ICR adjusted the cost burden estimate to $53,096,728. We have used this estimate to calculate the adjustment discussed above.

Type of Respondent- (% Record Responsibility)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General & Operations Managers- 10%	904,313	$63.70	$57,604,738
Compliance Officers-10%	904,313	$32.11	$29,037,490
Computer Occupations-5%	452,156	$38.37	$17,349,225
Statisticians- 5%	452,156	$37.42	$16,919,677
Biomedical Engineers- 20%	1,808,626	$44.76	$80,954,099
Customer Service Representatives- 10%	904,313	$16.01	$14,478,051
Information and Record Clerks- 15%	1,356,469	$14.11	$19,139,777
Supervisors of Production Workers- 10%	904,313	$29.86	$27,002,786
Misc. Plant a & System Operators- 15%	1,356,469	$23.51	$31,890,586
Total			$294,376,429

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, or operating and maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Based on past experience, it is anticipated that 190 full time equivalent (FTE) positions, including headquarters personnel, field investigators, and lab technicians, will be used to properly maintain and enforce the CGMP/QS final regulation. An average full time equivalent (FTE) employee is projected to cost FDA/CDRH $209,632,* which consists of the employee's salary and any overhead which accompanies that employee. The estimated annualized burden to government for this information collection is $39,830,080 per year ($209,632 x 190 FTEs).

*Based on the FY 2012 President's Budget Request All Purpose Table – Total Program Level table.

15. Explanation for Program Changes or Adjustments

The estimated annual number of recordkeepers has been adjusted from 8,924 to 25,986. Upon review of the data and this ICR we have determined that, for a more accurate estimate of recordkeepers, it is preferable to estimate the number of recordkeepers based on the number of establishments, rather than the number of owner/operators of those establishments. Additionally, because all registered establishment types must comply with the CGMP/QS regulations, we have included both domestic and foreign establishments in the estimate. A query of the Agency's registration and listing database for fiscal year (FY) 2012 shows that 15,113 domestic and 10,873 foreign establishments are subject to the regulations. Therefore, there are approximately 25,986 recordkeepers. The recalculation of the estimated annual recordkeepers using establishments rather than owner/operators and the inclusion of foreign establishments has resulted in an increase of 5,937,576 hours to the total recordkeeping burden. There has been no change to the existing program, including the respondents subject to the recordkeeping requirements. The adjustment is a result of recalculation of the respondents to more accurately and appropriately include the respondents subject to the requirements.

16. Plans for Tabulation and Publication and Project Time Schedule

The results of this collection of information will not be published.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.