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Journal of Power Sources 65 (1997) 101–107

JOURNAL OF POWER SOURCES

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A systems approach to creating reliable batteries for implantable medical applications

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Received 4 November 1996; accepted 19 November 1996

Abstract

Lithium batteries have been used to power implantable medical devices for over 25 years. During this period a system to ensure the reliability of battery performance has evolved, and continues to evolve, that embodies the use of quality systems, statistical sampling and testing of product, life testing and performance modeling. The development of a new lithium/carbon monofluoride battery product line will be used as an example of how these elements work together.

Keywords: Lithium primary batteries; Applications/medical; Reliability

1. Introduction

Lithium batteries have been used to power implantable medical devices for over 25 years. The battery chemistries that are manufactured at Wilson Greatbatch Ltd. (WGL) include lithium/iodine, lithium/silver vanadium oxide, lithium/thionyl chloride, and most recently, lithium/carbon monofluoride.

During this period a system to ensure the reliability of battery performance has evolved, and continues to evolve, that embodies the use of quality systems, statistical sampling and testing of product, life testing and performance modeling.

The batteries must be safe and reliable and long-term performance must be predictable. The development of new devices and the improvements in older device technologies require new chemistries to meet more complex performance demands. In addition, the increased need for a shorter time to market that has characterized most product development has become increasingly important for these power sources as well. All this must be accomplished with no reduction in the reliability of performance that has become the standard for lithium batteries for implantable medical devices.

The present state of the systems in which all these elements work together to ensure the production of high reliability power sources will be illustrated from a description of the development work for the new lithium/carbon monofluoride battery product line.

2. History

An earlier publication [1] described the approach used to make implantable lithium batteries as practiced around 1988. At that time the primary applications requiring implantable power sources were pacing and defibrillation. Defibrillation was in its infancy using the Li/silver vanadium oxide batteries, and pacing used the Li/I_2 system that had become the standard for that application. With recent advances in pacemaker technology such as the DDDRD capabilities (multiprogrammable units that pace and sense in both chambers of the heart and are capable of rate responsive pacing and shock), the need arose for a battery that had a higher discharge rate than the Li/I_2 battery while retaining its high capacity and safety characteristics. Other emerging applications likewise required power sources with similar characteristics. Li/CF_x, a battery system long used in commercial applications, was modified and developed for these emerging medical applications. Over this same period, changes in the development and manufacturing processes for implantable batteries were occurring as well.

At that earlier time, the reliability program began in the design phase of a new cell and involved a rigorous characterization of product safety and performance. Vendor qualifications were also begun to ensure the suitability of components for the batteries. The manufacturing process was designed to have frequent formal inspection and testing steps, and complete traceability of all components and operations was maintained. A final inspection and electrical characteri-

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PII S0378-7753(96)02602-X

zation were done to ensure compliance with in-house and customer specifications. Samples were taken from production to be discharged as life-test samples and the data were compared with accelerated test data.

The quality system used to control production at that time was based on the 'Good Manufacturing Practices' as issued by the US Food and Drug Administration [2]. These 'practices' require that appropriate facilities, organization, personnel, procedures and controls are used in the manufacturing process and that all practices are properly documented.

Since that time, two significant changes have occurred at WGL that have impacted the design and manufacture of implantable batteries: the implementation of a Total Quality Management (TQM) process, and the certification of the quality system to the ISO 9001 quality standard. The first change provided a quality management structure for the company, and the second change created a documentation structure that described how the other structure and the processes in the company functioned [3]. The first change also fostered a stronger team-based environment for process improvement including processes such as product development and manufacturing, and introduced people to hosts of quality improvement tools that made changes more efficient and effective. Having to document non-manufacturing processes as required by the ISO requirements made people aware of additional interactions and groups needed to make the development process more efficient, as well as all the other processes that impact and are impacted by the design and manufacture of the batteries.

3. The systems approach to improved implantable battery reliability

A quality system based on a TQM approach, and using a documentation structure required by ISO certification, results in a focus on documented continuous improvement. It provides an overall system that results in the production of batteries that meet all the requirements of the customers, both external and internal to an organization.

The TQM approach employed was initially founded on the teachings of Philip Crosby and has evolved to a more customized form using advanced quality improvement tools, but still embodying the basic Crosby elements. It is now known internally as the Quality Improvement Process (QIP). The following sections provide a brief description of the major aspects of Crosby and ISO that characterize the present system.

3.1. The Crosby elements

The elements of the Philip Crosby approach to quality improvement are documented in several books and embellished in course material available through Philip Crosby Associates, Inc.®. The approach is structured on a basic view that all work is a process embodying customer–supplier relationships that one continually strives to improve.

Table 1
The four absolutes of quality

1	The definition of quality is conformance to requirements
2	The system for causing quality is prevention
3	The performance standard is zero defects
4	The measurement of quality is the price of non-conformance

Table 2
The Crosby implementation steps

1	Management commitment	8	Zero defects planning
2	Quality improvement team	9	Zero defects day
3	Education	10	Goal setting
4	Measurement	11	Error cause removal
5	Cost of quality	12	Recognition
6	Quality awareness	13	Quality councils
7	Corrective action	14	Do it all over again

Crosby espouses four absolutes of quality dealing with the definition of quality, the system and the performance standard for the improvement of quality, and the measurement of quality. The four absolutes are shown in Table 1.

Crosby uses a quality improvement management structure that can overlay an existing functional organization structure to implement a fourteen-step process (Table 2) that becomes the system of how the company manages total quality.

3.2. The ISO 9000 Standard and elements

The International Organization for Standardization has developed a series of quality system standards (known as the ISO-9000 series). The focus of the standards is to provide a list of basic elements that are needed to satisfy minimum requirements for a TQM system [4].

Adoption of the standards by participating countries, and the companies resident therein, creates the basis for a universal baseline of what a customer could expect from a supplier in terms of the quality of the product or service that is supplied. The adherence to the standards is monitored through an initial certification and lifelong semiannual auditing process by third parties. At present the standards have been adopted by over ninety countries worldwide. Such universal adoption will make these standards a requirement for doing business. The ISO-9000 series contains five documents, of which three are the standards (9001, 9002, 9003) and the other two (9000, 9004) are an index and a set of guidelines. The 9001 standard is the most extensive because it covers companies that design and manufacture products.

The twenty elements of the 9001 standard are listed in Table 3. An examination of the details of the elements shows a number of common features that focus on the considerations of the responsibility element. The wording in the standards does not provide a cookbook on how to address each element. The negative aspect of this feature is that work must be spent in developing a system to satisfy the requirement of the ele-

Table 3
ISO 9000 elements

1	Management responsibility
2	Quality system
3	Contract review
4	Design control
5	Document control
6	Purchasing
7	Purchaser supplied product
8	Product identification and traceability
9	Process control
10	Inspection and testing
11	Inspection, measuring and test equipment
12	Inspection and test status
13	Control of non-conforming product
14	Corrective action
15	Handling, storage, packaging and delivery
16	Quality records
17	Internal quality audits
18	Training
19	Servicing
20	Statistical techniques

ment, but the positive aspect is that it allows a flexibility in the approach taken.

Documentation forms the basis for satisfaction of the ISO elements and achievement of certification. However, the flexibility allowed by the standard permits one to follow the old quality documentation dictum of 'say what you do and do what you say'.

If the documentation captures the former and you do the latter, then these two activities provide the basis for a high probability of a successful audit and subsequent certification. A recently published textbook offers pragmatic guidance on the implementation of the elements and on the role of the ISO elements as the basis for a TQM system [5].

4. Design control

This is one of the major systems in a company required by ISO certification. However, it can be well documented and structured, but quite inadequate in meeting the need for new products in shorter time frames. The development of a new lithium cell is a complex process that requires the balancing of many factors such as the power capability and safety, energy density and manufacturability, as well as the conformance to unique shapes for custom designed devices. In the case where the existing system may involve a serial movement of the idea to reality from marketing to R&D to engineering to manufacturing with transition through parochial department barriers, and all the delays and potential for error, one can use the corrective action system of the QIP to form a team to examine ways to shorten development times. Once the improved methodology has been developed — for example, a more integrated approach involving interdepartmental teams, the process can be documented in the form of the ISO structure that specifies the responsibilities and relationships.

This approach as now practiced can be described in the more familiar term of concurrent engineering. This is one of the more advanced tools for quality improvement and is consistent with the Crosby and ISO elements which emphasize doing things right the first time, a team based environment, and proper documentation. This tool has been refined to draw more and more people into the product development process and has stressed the value of doing as many steps in parallel as possible. The approach described earlier [1] had not embodied as integrated an approach as now practiced.

5. Modeling of battery performance

Part of the more integrated approach involves the use of battery performance modeling to guide the customer in selecting the most appropriate design for the application.

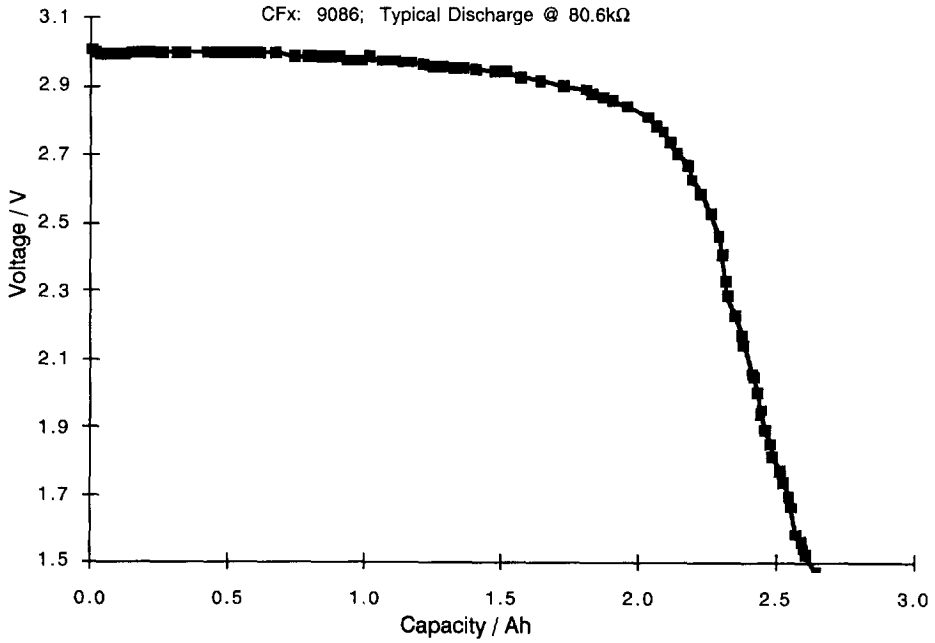

Fig. 1. Discharge curve for a model 9086 Li/CF_x cell.

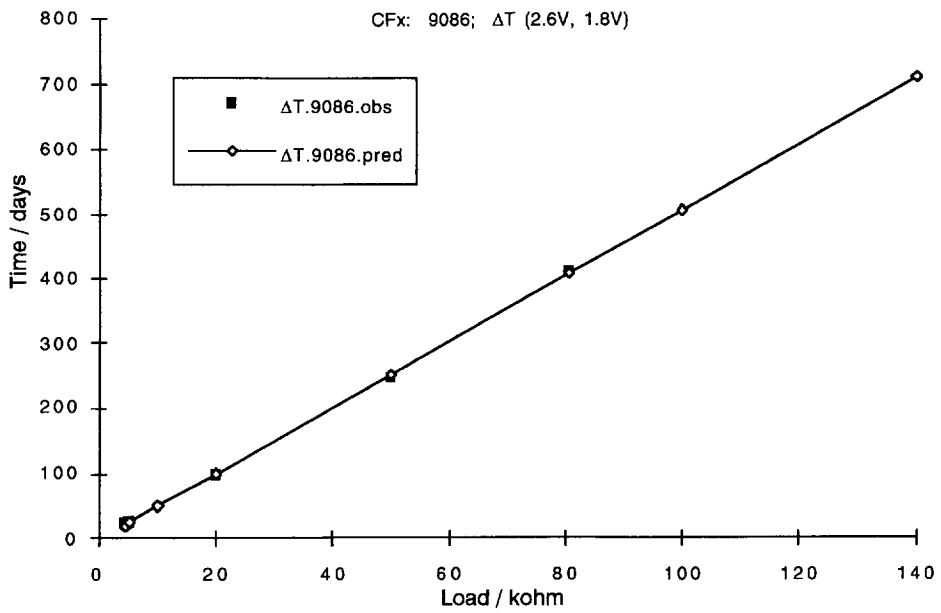

Fig. 2. Plot of time between ERI (elective replacement indicator) and EOL (end-of-life) values for an Li/CF_x cell.

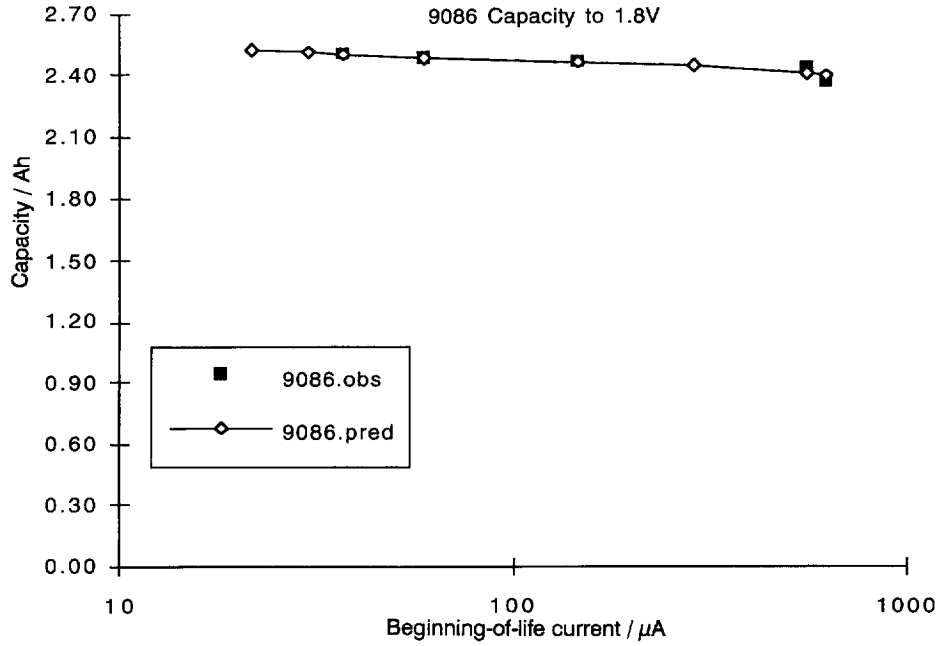

Fig. 3. Discharge capacity of Li/CF_x cell as a function of load.

Discharge data from the development of early prototypes form the basis for algorithms which describe the performance of cells of different shapes and volumes. Fig. 1 shows a typical discharge curve for an Li/CF_x cell. Analyses of similar data for various (typically heavy) rates of discharge extending over several years are used to develop preliminary models. These models are used to predict the performance of cells discharged under low rates.

Critical to cell users is the determination of the end-of-life (EOL) characteristics of the cell. Device engineers need to know the voltage profile for the cell discharged under various conditions, while physicians deem the elective replacement period critical (the amount of time between the elective replacement indicator (ERI) and the cell's end of life). This EOL signature is approximated from data collected during initial studies and refined as more data become available.

Fig. 2 shows a plot of the time (days) from a sample ERI (2.6 V) and a sample EOL (1.8 V) under various loads. Fig. 3 gives the observed and predicted capacity to 1.8 V of the CF_x cell discharged under various loads.

6. Process validation

As part of the more integrated and concurrent approach to cell development, new processes or modifications to existing manufacturing processes are identified in the early stages, developed and implemented. The implementation involves

drawing upon an aspect of the Good Manufacturing Practices that has received increasing emphasis in recent years, namely process validation [6,7]. Process validation requires that all aspects of the manufacturing process be examined with emphasis on qualifications of the equipment used in the manufacture, the manufacturing processes themselves, and the product. The approach described earlier [1] had a heavy emphasis on the product qualification which involved a variety of standard and abusive safety and environmental tests. Now, in addition, the manufacturing processes and the equipment that is employed are characterized as to their capability by the measurement of process capability indices, examination for variation over time, and the ability of the process to cope with operator and environmental variation. Specifications are also defined at this time regarding tooling, training, maintenance requirements, process monitors and the frequency of requalification. Product cannot begin to be manufactured until the processes and equipment have been qualified and the qualification documented in a report signed off by the quality assurance function in the company.

6.1. Equipment qualification

Lithium battery manufacturing for implantable medical applications requires equipment for a spectrum of operations including material preparation, component fabrication, component assembly, welding and cell testing. The equipment used in these operations can be items built in-house, purchased from outside the company, or purchased and modified.

The equipment qualification must demonstrate the ability to meet its defined specifications and throughput requirements defined by initial and projected production levels. Using the approach of Total Productive Maintenance, a value for the Overall Equipment Effectiveness (OEE) of the piece of equipment can be calculated and used as a basis for further improvement in equipment efficiency.

Equipment qualifications should demonstrate the features and satisfy the requirements listed as follows:

- all specifications for the equipment must be met;
- identify and examine critical equipment features that could affect process or product;
- equipment qualification must simulate actual production conditions;
- demonstrate the ability to consistently operate satisfactorily within the operation limits required by the process (power, voltage, force, throughput, etc.);
- examine and define issues regarding calibration, maintenance, adjustment requirement, monitoring and control;
- worst case situations should be identified and tested;
- repeatability must be demonstrated;
- all failures must be identified and evaluated to determine cause of failure;
- corrections should be made and additional tests run to verify equipment performs within specification;
- consensus basis involving users, designers, installers, qualifiers on all the above issues;
- establish OEE;
- characterize the design cycle time for its future use in the calculation of overall equipment effectiveness;
- written procedures governing the above items.

6.2. Process qualification

Once the equipment is qualified, the process in which it is used can be qualified. The process qualification requires that production parts, production operators, and variations related to parts lots, time of day, and other production related variables be part of the qualification. A process capability index needs to be measured to meet defined initial requirements and to use as a basis for further improvement of the process.

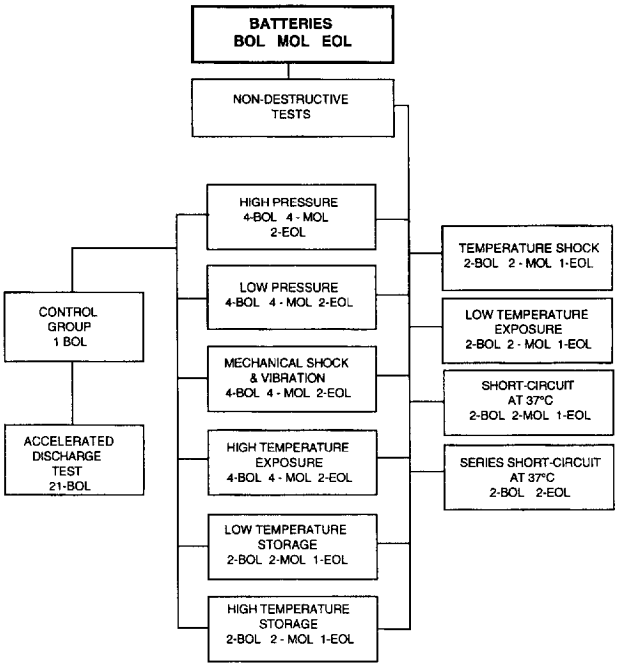

Fig. 4. Standard qualification test scheme for the Li/CF_x battery.

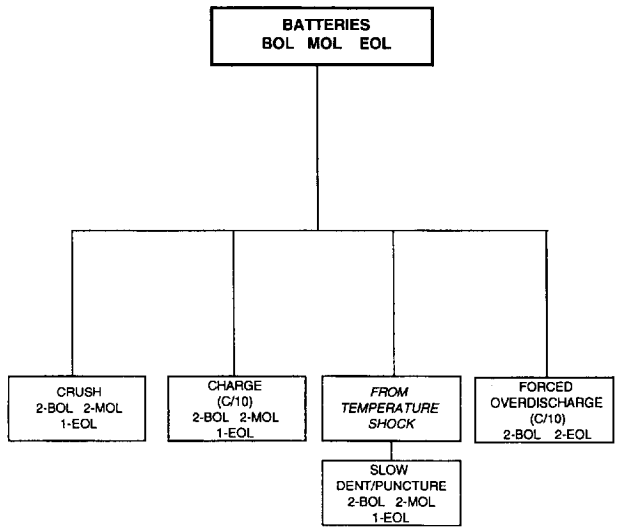

Fig. 5. Abusive test scheme for the Li/CF_x battery.

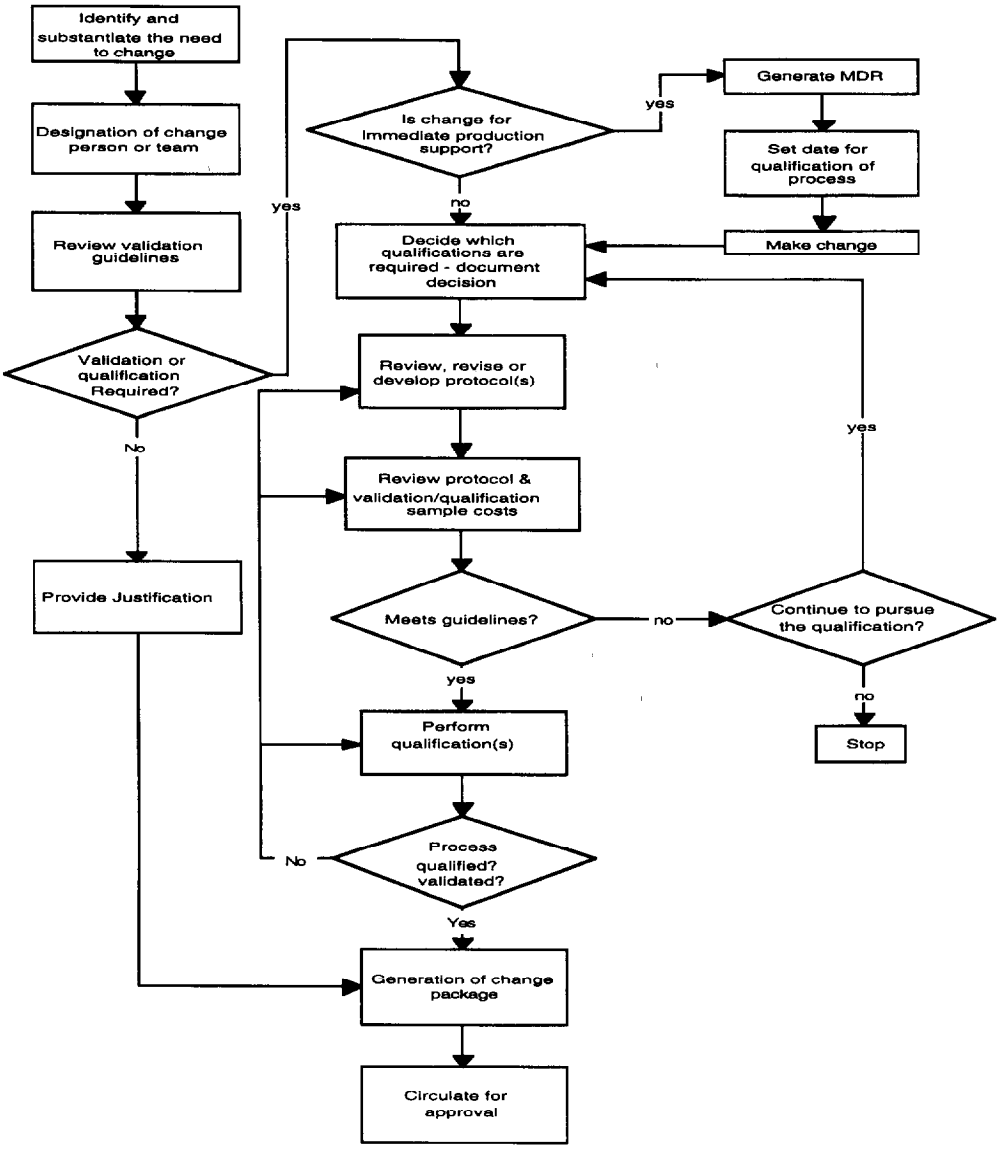

Fig. 6. Change control flow diagram.

Process qualifications should demonstrate the features and satisfy the requirements listed as follows:

- complete equipment qualification prior to initiating process or product qualifications;
- use production parts;
- use production operators;
- challenge the system (maximum throughput, setups/take-downs of fixtures, power loss, etc.);
- repeat the process over time with different operators;
- characterize the capability of the process (Cpk);
- properly train operators;
- establish process specifications;
- define how the process will be monitored;
- utilize quality tools (e.g. FMEA, capability studies);
- avoid reliance on similarities;
- evaluate all failures;
- evaluate process change regarding environmental impact (working environment as well as waste production);
- evaluate process change regarding ergonomic factors;
- evaluate process change regarding facility implications;
- evaluate process change regarding worker safety;
- require written setup procedures;
- employ written qualification protocols.

For the Li/CF_x cells, new processes had to be defined, modified or developed and qualified for cathode mix preparation (CF_x), cell assembly, welding (titanium), and of the electrical feedthrough.

6.3. Product qualification

The standard tests for product qualification for Li/CF_x cells include the following:

- thermal cycling from 70 to −40°C with a one minute transition time;
- high pressure testing at 830 kPa (120 psi);

- low pressure testing in a vacuum equivalent to an altitude of 50 000 ft;
- low and high temperature exposure;
- short circuit at 37°C;
- shock testing at 1000 *g*;
- vibration testing at frequencies ranging from 10 to 500 Hz;

Cells are subjected to these tests in three states of discharge: beginning of life, half and fully depleted. After each test, cells are visually inspected, measured for dimensional change, examined by X-ray and submitted for accelerated discharge testing. Fig. 4 shows a diagram for the test procedures. None of the tests shall result in cell leakage, rupture or short circuit.

Abusive testing is conducted to provide information on the safety margins for abuse of the cells. These tests are designed to drive the cells to destruction. Such abuses can include crushing, charging, forced over-discharge, also slow dent and puncture. Fig. 5 shows a diagram of the abusive test procedure.

6.4. Master validation plan

This is the high level document that relates how the equipment, process, and product qualifications relate to one another and how any changes that are proposed for an existing product must be assessed and qualified. The categories of changes are defined to provide guidance on whether a change requires qualification. The change control system flow diagram is shown in Fig. 6.

7. Conclusions

The previous emphasis on product qualification for new cell models and chemistries has continued, but in recent years has been augmented with two major changes: a continuous improvement driver that is part of a Total Quality Management system, and a documented design control system that is part of an ISO 9001 registered Quality System. In addition, Process Validation for critical processes in manufacturing operations is used to ensure that new processes work as expected when introduced. Modeling of battery performance is now used more intensively in the design phase to shorten the design cycle time as well as provide accurate predictions of cell longevity.

All these elements combine to produce a higher level of reliability for the production of lithium batteries for implantable medical applications.

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