

CONFIDENTIAL

**May not be reproduced without permission from Crimson Life Sciences
a division of TransPerfect Translations**

**Quality System Parity
Research Synopsis & White Paper**

2007-04-06

Author: Marc H. Miller
1.617.731.6920
mmiller@crimsonlanguage.com

Introduction

In March 2007, Crimson Life Sciences completed the industry’s first-ever survey of quality system parity among medical device suppliers¹. Based on historically high rates of certification to ISO 13485:2003 (36% of supplier base) and strong projected growth rates (20% of 9001 certified suppliers plan additional certification to 13485) across all classes of suppliers, research indicates the value of quality system parity for both manufacturers and suppliers.

Research Results

Research results are separated into key Objective and Subjective categories, followed by key research conclusions:

Key Objective Results

Item	Survey Result	Notes
Current Quality System Parity	36% of total supplier base certified to ISO 13485	Over 1/3 of supplier base certified within four years of standard’s introduction
Contract manufacturers and “Exempt” Suppliers Certified ²	45% of ISO 13485 certified supplier total	Due to service/product type, Exempt suppliers required to certify
“Non-Exempt” Suppliers Certified ³	55% of ISO 13485 certified supplier total	Non-exempt suppliers not required to certify – prevalence of quality system parity here indicates value of certification
Projected Growth	20% of ISO 9001 certified vendors plan additional certification to ISO 13485	Indicates dramatic growth in Non-exempt supplier certification

¹ “Quality System Parity” is defined as equivalent levels of quality system certification between manufacturer and supplier – in this case, supplier certification to ISO 13485:2003

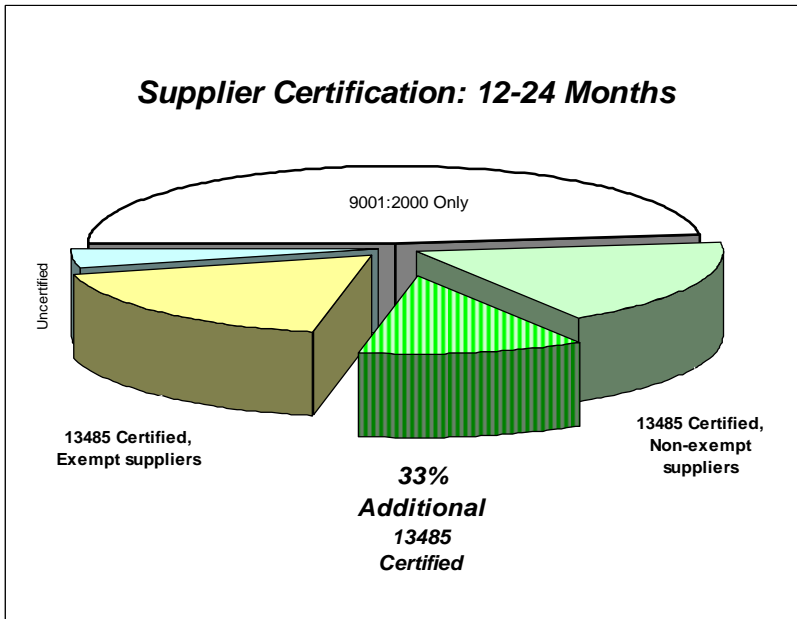
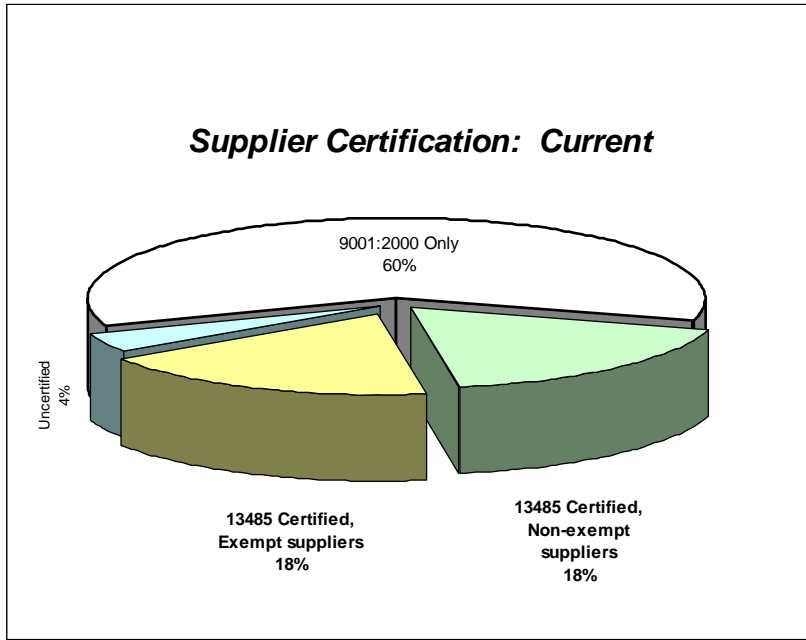
² Exempt suppliers are suppliers of sterilization or other products/services that are exempt from destructive incoming inspection.

³ Non-exempt suppliers are suppliers of components that are not exempt from destructive incoming inspection



CONFIDENTIAL

May not be reproduced without permission from Crimson Life Sciences
a division of TransPerfect Translations



CONFIDENTIAL

May not be reproduced without permission from Crimson Life Sciences
a division of TransPerfect Translations

Key Subjective Results

Notified Bodies actively encourage manufacturers to prefer ISO 13485 certified suppliers:

Registrars such as TÜV Rhineland are encouraging manufacturers to source from suppliers that are 13485 certified. Their belief is that if a supplier is certified to 13485 that should be sufficient for qualification without auditing.

- Linda Wertz, Senior Manager of Quality Assurance, Celera Corporation, an Applera Business

Manufacturers perceive value in quality system parity:

The supplier still needs to prove themselves, but 13485 certification helps to establish a common language for discussion of quality requirements. Seventy-five percent (75%) of our suppliers are certified to 13485 – for us, it's an important prerequisite.

- Tracy Ohmdal, Director of Quality, Genicon

Suppliers perceive value in quality system parity:

We are getting dozens of calls a week and everyone is asking about certification to ISO 13485.

- Chrissy Kling, QA Manager, A.P. Extrusion

Certification to ISO 13485 means that very soon we will be positioned to support our clients' dock-to-stock initiatives. We also know that incoming inspection is less burdensome with certification to 13485. Based on industry conversations, certification to ISO 13485 also helps in a CE audit – and we anticipate growing our EU sales as a result.

- Adam Trenz, Quality Manager, Excel Medical Products

Key Research Conclusions

- Current international standards and regulatory guidance require stringent supplier control, including risk management (see *Regulatory Background* section, below)
- Particular rigor should be applied to outsourced processes that may affect product conformity – especially processes related to *design, manufacture, packaging or labeling of a medical device, assembling a system, or adapting a medical device before it is placed on the market and/or put into service* (see *Regulatory Background* section, below)
- Regulations and regulators favor quality system parity as one means for demonstrating appropriate risk management and supplier control
- Manufacturer purchasing practices indicate the value of quality system parity
- Current rates of ISO 13485 certification across all supplier types indicates value of quality system parity
- Regulatory and economic value of quality system parity supports strong projected growth rates of ISO 13485 certification through 2009 and beyond

Research Background

The Quality System Parity Survey was conducted according to the following specifications:

Survey Initiated: 1/29/07
Survey Concluded: 3/28/07



Title: Quality System Parity Research White Paper
Author/Responsible: MHM

Page 3 of 6



CONFIDENTIAL

May not be reproduced without permission from Crimson Life Sciences
a division of TransPerfect Translations

Survey Methodology:	primary and secondary research
Total Suppliers Surveyed:	429
Supplier Types:	contract manufacturers; component manufacturers; packaging suppliers; sterilization suppliers

Summary: Survey specifications indicate information drawn from a significant number of suppliers, spanning a broad range of types.

Regulatory Background

Following are the relevant references that, taken together, define the substantial regulatory value of quality system parity:

ISO 13485:2003

ISO 13485:2003 requires control of suppliers and outsourced processes:

7.4.1 Purchasing process

The organization shall establish documented procedures to ensure that purchased product conforms to specified purchase requirements.

The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation, and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

4.1 General requirements

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system (see 8.5.1).

ISO 13485:2003 also indicates specific risk management requirements:

7.1 Planning of product realization

The organization shall establish documented requirements for risk management throughout product realization. Records arising from risk management shall be maintained (see 4.2.4).

NOTE 3—See ISO 14971 for guidance related to risk management.

Summary: ISO 13485 requires stringent supplier evaluation and control. Manufacturers are required to control outsourced processes that may affect the conformity of the product – ISO 14971 defines these processes as:
design, manufacture, packaging or labeling of a medical device, assembling a system, or adapting a medical device before it is placed on the market and/or put into service

ISO 14971

ISO 14971 firmly establishes the manufacturer's responsibility for risk management of all outsourced processes. The standard is clear on this subject in the "definitions" section when it states:

CONFIDENTIAL

May not be reproduced without permission from Crimson Life Sciences
a division of TransPerfect Translations

2.6

manufacturer

natural or legal person with responsibility for the design, manufacture, packaging or labeling of a medical device, assembling a system, or adapting a medical device before it is placed on the market and/or put into service, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

Summary: By definition, manufacturers are responsible for the risk management processes of their suppliers according to ISO 14971.

GHTF/SG3/N15R8

Published guidance from the Global Harmonization Task Force (GHTF/SG3/N15R8) further highlights manufacturer responsibility and appropriate risk management for outsourced processes:

Processes required by the quality management system and performed by suppliers to the manufacturer are the responsibility of the manufacturer. Risk management activities relating to any process within the quality management system are ultimately the responsibility of the manufacturer.

Risk management activities should identify hazards and evaluate risks, including those potentially introduced by suppliers early in the product realization process.

Risk management roles and responsibilities of the manufacturer and supplier should be defined as part of the purchasing requirements. In addition, prescribed risk control measures derived from the risk management process during product realization should be included in the purchasing requirements as part of the purchasing information.

Summary: Manufacturers are responsible for the risk management processes of their outsourced vendors. Manufacturers should identify and control risks introduced by suppliers. Risk information generated as part of product realization should form input for purchasing requirements.

Notified Body Guidance

Published guidance requires Notified Bodies to undertake supplier (subcontractor) risk assessment:

The two main issues a Notified Body should address when reviewing subcontractors are:

- a) Whether the subcontractor has a substantial involvement with the design and/or production of the device.*
- b) Whether the subcontractor is undertaking the supply of a part, material or service, which may affect the compliance of the device with the essential requirements.*

If the answer to both a) and b) above is NO, no further action is required.

If the answer to a) or b) above is YES, then the Notified Body must evaluate whether there is sufficient evidence provided of the competence of the subcontractor to undertake supply of the part, material or service in relation to the medical device(s) in question. The evaluation will consider various matters including the control exercised by the manufacturer over the subcontractor and the certification held by the subcontractor.

If the supplier has “substantial involvement” with any of the following: *design, manufacture, packaging or labeling of a medical device, assembling a system, or adapting a medical device before it is placed on the market and/or put into service* (as defined by ISO 14971), then it is subject to Notified Body risk management assessment. For example, Notified Body guidance specifies:

CONFIDENTIAL

May not be reproduced without permission from Crimson Life Sciences
a division of TransPerfect Translations

Due to the compliance implications for the essential requirements of the MDD and the IVDD, Notified Bodies consider translation to be an 'important outsourced service'...This makes translation providers subject to the outsourced vendor risk management considerations of ISO 13485:2003 and ISO 14971.

Summary: Notified Bodies are required to investigate the qualification of subcontractors. They are instructed to consider supplier certification as part of this investigation. Notified Body guidance and ISO 14971 specifies labeling as a process that requires risk management consideration. Suppliers of labeling translation are one example of a service provider whose qualifications must be investigated by Notified Bodies.

About the Author

Marc H. Miller is the founder and President of Crimson Life Sciences, a division of NY-based TransPerfect Translations. Crimson is the only translation company in the world to hold certifications to ISO 9001:2000, ISO 13485:2003, and an official endorsement to ISO 14971:2000. Mr. Miller holds a BA in languages and literature from Harvard University and an MBA from the Scottish Business School in Stirling Scotland. While working as a Sr. Research Fellow with the international strategy consulting firm, SIAR, he authored strategic assessments for European and US medical technology firms. Crimson's specialized approach to medical technology translation has been featured in industry publications such as Medical Device & Diagnostics Industry, Medical Products Outsourcing, and Orthopedic Design & Technology.

(end)