

MEDTECH

Supplier Monitoring and Development

Christopher Staab
Director, Global Quality
Interview by Darwin Shurig
President Shurig Solutions Inc.



INSIGHTS

2020

Do you have a challenge currently with a strategic initiative relevant to Quality or have Quality Talent needs?

Let's schedule a Needs Analysis Conversation!

Please feel free to schedule directly [on our calendar](#).



SHURIG SOLUTIONS, INC.

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DARWIN SHURIG

PRESIDENT - SHURIG SOLUTIONS INC.

Darwin understands the key qualities that companies look for in candidates to grow market share, while enhancing their positive culture and team environment. He has a clinical background of over 20 years, including 15 years of sales experience within: medical device, diagnostics, medical distribution, and sleep therapy; 8 years in sales management success; 3 years in operations; and extensive experience in negotiations and business development.

SSI has been growing for over 5 years with a focus on RA, Quality and Engineering within the Medical Device and Pharma industries. With over \$2.5 Million in revenue and a 91% offer acceptance rate, SSI is helping companies find unique talent that makes a difference, brings value and decreases the risk of a mis-hire.



CHRISTOPHER STAAB

DIRECTOR, GLOBAL QUALITY, COOPERSURGICAL

Chris has 15+ years of Medtech Quality experience with a progressive career for compliance, risk management, and supplier development with strong business acumen.

Demonstrated success record in:

- Managing supplier performance and evaluations for 40 sites and over 6000 suppliers
- Developing innovative ways to reduce supply base risk and increase supplier quality levels.
- Harmonizing and standardizing across multiple businesses to reduce Cost of Poor Quality in Supplier Quality
- Overhauling the Health Hazard Evaluation, Product Restriction, and Recall processes
- Providing documentation and conformance to standards to achieve 510k approvals and product launches

A leader, family man, and a competitor (Chris was the Captain of the Men's Basketball Team at Roger Williams University), Chris has an impressive breadth of experience and excellent insights to share.

[Link to Full Webinar](#)

Regulations & Purchasing Controls

FDA regulation, 21 CFR Part 820, says, "**Each manufacturer shall establish and maintain procedures to ensure suppliers can meet the requirements.**" As manufacturers, we need to have procedures to make sure that the suppliers can meet what we're asking them to do. The next part is we need to evaluate and select those suppliers based off their ability to meet those requirements.

[Video Link](#)

ISO 13485 Evaluating Data Trends

Staab: ISO 13485:2016, Section 7.4 goes into purchasing and the purchasing process. It is very similar to QSR 820 in that you need a procedure that conforms to specified purchasing information. You need to document what you are going to do, communicate with the relevant supplier on what is needed and establish a criteria for the evaluation and selection of suppliers. The criteria should be based off the supplier's ability to provide the product relevant to your requirements, supplier performance, the effect on the purchased produce relevant to the finished product and then monitor and re-evaluate your suppliers.

Darwin: Communicating back to your suppliers, setting up what SCAR will look like, solve the problem, and then remediate it for improvement to make the issues go away.

Staab: Absolutely, it is all about the trending data, how you manage it, looking at the data. Most importantly, if you are collecting the data, use the data because it will guide you.

[Video Link](#)

Trending

Non- Conformance Trending

Staab: Quoting the regulation, "the nonfulfillment of purchasing requirements shall be addressed with this power proportionate to the risks". This is a risk-based decision on NCR and how you manage it; define that NCR and grade it. Set up your action plan, proceduralize your action plan on what you're going to do with those types of nonconformances.

Make sure you don't miss the regulatory piece; if the supplier changed material or manufacturing location, there can be regulatory implications even if the NCR process is fully functional and compliant.

Once you get that data, start tracking it and you'll start to see trends and challenges in certain areas. There's all different ways of classifying these failures: dimensional concerns, corrosion concerns, short circuits, tool marks, etc., but getting the data is only half the talks. Using the data and then taking action with your suppliers to fix challenges is the other half.

[Video Link](#)

Developing Scorecards

Supplier performance in meeting requirements for the purchase goods shall be monitored and the results of the monitoring shall be an input to the revaluation process.

Performance Factors to consider:

- **Non-Conformance/ Non-Conformance rate (NC/Receipts)**
- **Supplier CAPAs**
- **Timeliness of those SCAPAs.** Were they late? Were the responses adequate? Did they go effective or ineffective?
- **Supplier Fault Product Hold or Field Actions-** Did they cause challenges for you in your finished good?
- **Organizational-** Internal audits, external audits, and then third-party results. Did they have any 483 for other matters?
- **Fill Rate**
- **On-Time Delivery**

[Video Link](#)

Trending

Initial Supplier Evaluation

Staab: You need to evaluate every supplier, what they are providing and understand their QMS.

Shurig: When you are picking a supplier, what does that timeframe look like to pick a supplier?

Staab: The Earlier the better. You need to get in with your advanced sourcing team or NPD team and understand who they are selecting and work with them early in the process; early understanding of the supplier's capabilities is critical to success.

[Video Link](#)

Supplier Evaluations Post COVID

Staab: We see all the time now, "Due to COVID-19 we will not be allowing any visitors at this facility". How are you supposed to do a quality management system audit or an onsite audit where you can't get onsite?

Shurig: I have witnessed some scenarios of a clients moving to video auditing or creating a combination of remote and onsite.

Staab: Yes, you must understand the challenges and then put work arounds in place to manage them. Many suppliers are open to uploading files in advance. You need to work with your manufacturing sites and what supplier challenges they are having up front, so you know where to focus.

You must be knowledgeable of the suppliers process up front so you can build efficiency to your process up front and then use electronic tools, such as Box, WebEx, Video Chat, and Zoom. For Example, many suppliers are open to taking the computer around the manufacturing facility for an audit.

[Video Link](#)

Evaluation

Supplier Surveillance Evaluations

Staab: Surveillance Evaluations: this is the piece of monitoring and leveraging our scorecard to determine which suppliers need to get out to because they are high risk. This allows you to see what challenges they are having and work with them to make sure they have the proper controls in place.

Create a schedule for your suppliers based on risk and then stick to it while leveraging your time per supplier based on your performance monitoring.

[Video Link](#)

Shurig: How many different sets of eyes do you have looking at that data that you are obtaining for your suppliers?

Staab: From a performance monitoring standpoint, we review the data as a cross-functional team for all sites with all of our sourcing counterparts so everyone is aware of how that supplier is performing. Additionally, you want to make sure NPD understands how relevant sustaining suppliers are doing for future projects. The team is looking at data, understanding it even if it is just escalating up key data points to those outside of the cross-functional teams, it is important.

Getting Suppliers to Manage Their Suppliers

Shurig: Chris, how do you get your suppliers to effectively monitor and manage their suppliers?

Staab: Great question! In Medtech, we are often telling our suppliers who to use which adds an entirely different dynamic. It comes down to communication; you need to partner with your suppliers, make sure they know their responsibilities and set up appropriate supplier controls for whatever is coming in their door.

[Video Link](#)

Shurig: I think the successful implementation comes down to proactivity versus reactivity, right? Do you have success examples relevant to giving more business to supplier that you are not having issues with?

Staab: Absolutely and we leverage those performance criteria with like suppliers. They are all competing for the same business so make sure you leverage performance monitoring and leverage the data in any way possible to make sure your suppliers are continually reaching for "best practices".



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