



CONTRACT MANUFACTURER SUBSCRIBER PROGRAM

A Risk Reduction Program Contract Manufacturers Can Leverage to Ensure Quality Down Their Supply Tiers

Driving Supplier Oversight and Quality Performance Into the Supply Chain

The MedAccred® Contract Manufacturer Subscriber program builds upon the current MedAccred critical process accreditation program. By using the MedAccred Accreditation program, contract manufacturer subscribers can benefit from the same level of supplier performance and assurance within their critical process supply chain as the OEMs. Contract manufacturers with suppliers that deliver critical processes covered by the MedAccred Accreditation program can require these 2nd and 3rd tier suppliers to become MedAccred Accredited.

- Cable & Wire Harness
- Heat Treating
- Printed Board Assembly
- Plastics Extrusion
- Plastics Injection Molding
- Plastics Mechanical Assembly
- Sterilization
- Sterile Device Packaging
- Welding

Subscribing Contract Manufacturers benefit from the program in the following ways:

- Reduced cost while delivering improved quality
- Improved process control down the medical device supply tiers
- Enhanced role as a strategic supplier with greater assurance of sub-tier supplier controls, contributing to improved product quality and patient safety
- Greater insight to audit information within the critical process(es) of choice
- Elevates your company's value to OEM customers

To learn more about how your company can benefit from MedAccred,
Call: +1-724-772-1616 Email: MedAccred@p-r-i.org Visit: p-r-i.org/medaccred



Supply chains are becoming extensive and complex, which makes ensuring a high level of quality throughout the supply chain and a product's life cycle challenging...Regulatory agencies do not perform routine inspections of component manufacturers, so the burden of regulatory compliance is on the sponsor company."¹

1 "Overview of Quality System Regulations (QSR) for Medical Devices," Beckie Ellis, FDA Medical Device Industry Coalition

MedAccred was developed by OEMs:

- Baxter
- BD
- Boston Scientific
- Edwards Lifesciences
- Medtronic
- Philips Healthcare
- Roche Diagnostics
- Stryker



STAKEHOLDER ROLES

	Establish Policies	Participate in Management Council	Determine Audit Criteria	Select Auditors	Access Audit Data	Vote on Accreditations	Participate in Task Groups
OEM SUBSCRIBERS	✓	✓	✓	✓	✓	✓	✓
CONTRACT MANUFACTURER SUBSCRIBERS					✓*	✓*	✓
CRITICAL PROCESS SUPPLIERS							✓

*Limited to Sub-Tier Suppliers

Enhancing Resiliency Throughout the Medical Device Supply Chain

The Contract Manufacturer Subscriber Program increases visibility and collaboration down supply tiers to augment supply chain sustainability.

Value of Being a Contract Manufacturer Subscriber

Contract Manufacturer Subscribers have an increased level of access to MedAccred® systems that enhance the value of the total program. Contract Manufacturer Subscribers have access to all of the audit details within their subscribed critical processes.¹ They will also be able to participate in reviews, provide comments, and vote on pending accreditations within their subscribed processes. Access to audit reporting details can provide informative decision-making as it relates to managing your suppliers.

¹ Accredited suppliers can opt out of sharing their audit detail for "conflict of interest" reasons.

Oversee your supply chain to improve product quality and enhance patient safety!

Contact MedAccred to learn more!

Call: +1-724-772-1616 **Visit: p-r-i.org/medaccred**

Email: MedAccred@p-r-i.org

Contract Manufacturers and their sub-tiers are responsible for over 70% of all manufacturing in the Medical Device Industry.



The creation of a new MedAccred Contract Manufacturer Subscriber program is an exciting development that is going to help contract manufacturers within the medical technology industry develop greater oversight and control across their supply chains. This innovation will go a long way towards supporting quality and patient safety across the medical industry."

DANNETTE CROOMS

Vice President

Global Supplier Quality
Edwards Lifesciences