Quality and Regulatory Affairs

Quality and Regulatory

SP Medical's management system takes into account all the demands on and expectations faced by providers to the global medical devices and pharmaceuticals industries:

- We are certified to the ISO 9001, ISO 13485 and ISO 14001 standards.
- We have CE mark certification under the Medical Device Directive 93/42/EEC as amended by 2007/47/EEC.
- We are an FDA-registered contract manufacturer.
- We comply with FDA Part 820 (QSR).
- We comply with the Global Harmonization Task Force Guidelines.
- We have MSA accreditation.
- We build and maintain our cleanroom environments in accordance with ISO 14644 and ISO 14698.

Quality Activity Plan

Our project management model includes a Quality Activity Plan (QAP) that defines requirements for the relevant product.

Our QAP complies with the requirements set out in EU-GMP/GDP/GTP, FDA Part 820 (QSR) and the Medical Device Directive 93/42/EEC as amended by 2007/47/EEC.

This means that we prepare documentation in the form of Design History File (DHF), Device Master Record (DMR) and Device History Record (DHR).

Other Capabilities

For information about our other capabilities and 50 years of experience within injection moulding and plastics please check our website www.sp-medical.dk.