50 new combo products delivered to market.

Case Study

Compliance for Combination Products

INDUSTRY

Pharmaceutical

Medical Device Manufacturer

SERVICES

Commissioning & Qualification

Product Development

Remediation

SKILLS

ISO Compliance

Project Management

Test Method Validation

The Challenge

A large pharmaceutical organization formed a new device-manufacturing division and requested Oxford's support in achieving compliance for a brand new range of combination products. The scope of the project required a large group of consultants to assist the client with preparing new product lines to be compliant with ISO 13485, ISO 14971, and 21 CFR Part 820. Several project leaders were also required to manage the development of more than 50 products within their portfolio of drug-delivery services. Our client needed the right partner to help accelerate the development lifecycle and get their products to market more quickly.

The Solution

Through a careful vetting process, Oxford placed over 40 senior-level consultants, each holding a minimum of 7 to 8 years of experience, with knowledge in both pharmaceuticals and medical devices. We provided experts with an in-depth understanding of medical device compliance, and the ability to execute a hands-on approach to meet project deliverables. Our team supported the development of various combination products, including: pre-filled syringes, autoinjectors, subcutaneous patches, pumps, dry powder and metered dose inhalers.

Project workstreams covered:

- Material selection and supplier engagement
- Human Factors Engineering (IEC62366) and ISO 13485 compliance
- Design History File (DHF) remediation (legacy products) and compilation (new devices)
- Design Control (input, output, testing & verification) and implementation of 21 CFR 820 Part 4
- Improving the level of ISO 14971 compliance within this combination-product business unit

The Result

All project goals and requirements were successfully reached. Over a 4-year period, our client retained all 40 consultants. The consultant team was so effective that each person received a 6 or 12-month expansion on their contract. Working in close collaboration, we helped qualify and deliver 50 new combination products to market within 2 to 3 years.

By evaluating requirements, providing the right high quality candidates, and maintaining ongoing communication throughout the project, Oxford became a preferred partner, with multiple consultants actively supporting new and ongoing objectives within this device-manufacturing business unit.

About Oxford: Oxford is known for our unmatched ability to deliver *The Right Talent.* **Right Now.**® As a leading recruiting and consulting company with offices across North America and Europe, we focus on proactively building a network of highly skilled professionals so that we can immediately connect our clients to the expertise they need and provide rewarding opportunities for our consultants. We leverage over 30 years of recruiting expertise and specialize in fields where superior resource solutions are most in demand.