



Platelet FUNCTION TESTING

PRODUCT DESCRIPTION

Consumables for platelet function diagnostics. The approach is a one-to-one transfer of a valid set of systems and the development of a new automated injection molding and assembly process.

INDUSTRY & FUNCTIONALITY

It is an in vitro diagnostic device for platelet function testing.

REQUIREMENTS & CAPABILITIES

- Requirement management (ISO, FDA, customer and country specific)
- Interface management
- Qualified equipment and proven processes
- Consideration of scale up from project initiation onwards
- Global footprint production
- Production in grey room
- Proven automated and manual assembly
- Total management of global supplier base

DIFFERENT CHALLENGES

- A process transfer was carried out with the previous supplier due to a production shutdown caused by the current supplier
- The injection molding automation was introduced once the design was finalized
- The review of various production processes used in assembly was carried out in parallel

TECHNOLOGY & PROCESS

- Transfer of assembly processes
- Automation of injection molding and assembly process - Scale up capability
- Tool making
- Injection molding
- Manual & automated Assembly for back-up and scale-up purposes
- Custom packaging and labeling