



**NUVALEZ**  
INTEGRATED SOLUTIONS

## Excellence as Standard

*With our in-house expertise we can help navigate the complexities of clinical trials right through to commercialization and beyond. Our team of experts assist our clients with Supply Chain Quality, Regulatory, and Customs and Tax as they launch their products globally.*

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# Clinical Trials

- Management of API, Drug Product & Packaging
- Internal link between CMC and clinical operations departments
- Analysing gaps in supply-chain and recommending action plans to close
- Ensuring randomisation and site inventory levels are respected and reported accurately
- Liaising with CRO and IRT as the unblinded partner in the process
- Scenario planning for up-coming and on-going studies to ensure that senior leadership has the most accurate information for decision making



# Serialization

- Provider Selection
- Process Mapping
- Trouble-shooting
- Compliance with Regulation
- De-commissioning
- Transferring from one provider to another



# Operational Excellence

- Sales and Operations Planning
- ERP Management
- Smartsheets Reporting
- Quality Unit Staff Augmentation
- Method Validation/Transfer
- Commercial Release and Stability testing
- Analytical Development
- Lab Software
- Lab Equipment Qualification/Requalification
- Leadership and Management
- Inventory Management
- Scheduling
- Continuous Improvement: Kanban system, 5S, 5Why, Gemba, PDCA, Kaizen, Right First Time, Problem Solving, Visual Management, 7 Wastes

# Launch Management

- Vendor Selection
- Vendor/CMO Management
- Artwork Co-ordinators
- Shipping Studies
- Logistics
- Planning and Forecasting
- Supply Execution
- Inventory Optimization





# Commercialization

- Supplier Management
- Logistics Management
- 3PL Management
- Planning and Forecasting
- Sales & Operations Planning
- ERP Management



# Quality Assurance

- Quality Unit staff augmentation
- Quality Management System (QMS) development, assessment, and optimization
- Batch review and disposition, excluding Qualified Person (QP) release
- Root cause investigations and Corrective and Preventive Action (CAPA) planning and execution
- Annual product reviews/reports
- Training
- GMP auditing
- Inspection Readiness



# CMO Auditing

- GMP Auditing of CMOs globally
- Cost effective solution for local auditing in US, EU, India and China
- Audits done by experts in local language

