

Together to the top

Progress-PME is an independent project management and consultancy company with customers in life science, primary in (bio)pharmaceutical, medical device and healthcare industries. The company was founded in 1999, and provides support throughout the entire product life cycle from process development to commercial production and, at end-of life, decommissioning.

It is our mission to support the Life Science Industry, in the interest of patients, in bringing innovative, effective, safe and affordable medicines to the market. Our vision is to excel in supporting our clients with reaching their goals. With our broad knowledge and experience, coupled with a practical attitude, perseverance and flexibility, we strive for high-quality services and multidisciplinary advice.

Quality is vital for Progress-PME. In December 2008, Progress-PME obtained its ISO 9001 certification and since then the certification has been renewed yearly. In case our employees are working on projects at the client's site, obviously, the client's quality system is leading.

Services

A structured approach and close collaboration with client's employees, combined with a high degree of involvement, make our services a great success.

- ✓ Project management
- ✓ Interim management
- ✓ Consultancy
- ✓ Training
- ✓ Gap analysis using Quickscans

Progress-PME stands for short timelines, high quality and realistic costs. We advise and implement together with the client. This pragmatic approach, while maintaining high quality standards, results in an effective solution which is fit-for-purpose and focussed on the needs of the client.

- ✓ Leading multidisciplinary projects using Prince II principles where necessary
- ✓ Optimization of processes using Lean Six Sigma
- ✓ Gap analysis using in house developed toolkits and templates
- ✓ Provide team leads and team members

The team

Progress-PME consists of a group of about 50 professionals that includes engineers, project leaders, project managers, interim managers and consultants, selected on their professional knowledge and communicative skills. All share our company core competences: flexibility, customer focus, expertise and integrity. The staff, strategic and tactical, are multidisciplinary in both project management as well as expert in one and usually more subject matters. It is a close and enthusiastic team that supports each other by sharing their knowledge, evaluating projects and exchanging experiences. Our professionals are trained regularly to keep up-to-date with current quality guidelines, developments and trends, and are used to adapting to the customer's quality systems.

Customer Satisfaction

We use customer feedback to continuously improve our services. We go to great lengths to build and maintain good relationships with our clients. Progress-PME is highly valued for its constructive way of working. Working on a project as a joined team with the client is our strong preference. This enables us to transfer knowledge and increase internal know-how, e.g. by coaching and training-on-the-job.. We improve the intrinsic (GMP) culture and empower staff.

Fields of Expertise

As Progress-PME, we want to deliver successful projects and services. We can only do this if we know exactly who the customer is and what the customer wants. We offer integrated, knowledge-driven and pragmatic solutions, followed by an effective implementation phase. Our areas of expertise include:

- ✓ Early and late stage CMC (process and analytical) development
- ✓ Regulatory
- ✓ Manufacturing
- ✓ Quality Control
- ✓ Quality Assurance & Quality Management
- ✓ Engineering (including cost engineering)
- ✓ Logistics
- ✓ Lean Six Sigma and OPEX programs.

Quality

Tightened legislation and regulations and increasing competition in the market are a driving force to monitor quality increasingly and to improve it where possible. Progress-PME helps to implement a quality improvement programme including:

- ✓ Prepare for Inspections from regulatory agencies and execute mitigation activities
- ✓ Workshops and (GMP) trainings
- ✓ Build / improve the Pharmaceutical Quality System (PQS) and associated SOPs
- ✓ Build/ adapt GMP documentation, including the batch documentation, operating instructions and logbooks,
- ✓ Perform audits of e.g. API suppliers, CMOs
- ✓ Computerised Systems Validations (CSV) experts

CMC

Progress-PME provides technical know-how and expertise in the development, testing, documentation and registration of a new pharmaceutical product, the production process and associated analytical methods. Our professionals combine years of experience in designing and scaling-up of production processes, developing new (biotechnological) products and project management. We advise on, and co-ordinate the activities, recognise the bottlenecks and help in finding pragmatic solutions.

- ✓ Product&Process and/or Analytical development according to Quality by Design principles
- ✓ Process Performance Qualification & Verification

including cleaning validation

- ✓ Technology Transfer
- ✓ Regulatory Submission Support
- ✓ Performance improvement of QC procedures and methods

Engineering

Progress-PME engineers design and build production facilities and systems and improve the reliability and compliance of your current technical infrastructure. The secret of our success lies in the fact that we compile a construction team that includes members from the client, contractors and advisors. This integral approach produces a co-operative team with all the necessary disciplines. By involving the client closely in the design phase, Progress-PME translates the client's needs to the constructors in the construction phase.

- ✓ Conceptual engineering
- ✓ Basic Design
- ✓ Construction of a facility (building/ expansion/ relocation)
- ✓ Commissioning & Qualification

Lean Six Sigma / Operational Excellence

Progress-PME has extensive expertise in the field of lean six sigma and we know the pharma industry.

We know CMC, production, packaging, QC, QA, validation and qualification, logistics and engineering. Our enthusiastic process thinkers act comfortably and sensitively at both shop floor and at senior management level.

We offer:

- ✓ Lean deployment / OPEX program
- ✓ Execution of lean six sigma DMAIC projects
- ✓ Value stream mapping (current state / future state / Action plans)
- ✓ Root cause investigations
- ✓ Kaizen facilitation
- ✓ Visual factory / lean operations management
- ✓ Green belt or black belt project managers