



Global Pharma Networks Services



... adding value to your business



Vision
To use our knowledge and experience of industry to leverage sustainable benefits for our clients

New Pharmaceutical Start-up

Over the past 20 plus years GPN SME's* have been involved in numerous new facility start-ups and expansions. In particular, we have been involved in the areas of planning and management of projects, validation and qualification of both the facilities and the processes, compliance and regulatory readiness and the operational start-up of the facilities.

Site Selection

GPN has a defined and proven methodology for site selection. This is based on the experience we have gained over the years and our knowledge of the local environment. Our experience in this field also means that we are in an ideal position to interface and coordinate with all the governmental and regulatory bodies involved in this process. We have been involved in this for a number of confidential clients.

Integrated Project Timeline

Integrated Project Timelines are a critical success factor for both new facilities and expansions. The focus is to provide a clear plan for facilities and operations start-up right through to product launch. All the other project plans (design, construction, validation, process scale-up, process validation, exhibit batches, regulatory, etc) are integrated into one cohesive whole. Risks, problems and conflicts are identified and solutions are proposed. GPN SME's have over 20 years experience in the development of integrated timelines and what the issues that need to be resolved. This experience has been gained in both new sites, and on expansions, and on new product and process introductions to existing sites, in a number of countries. GPN's experience can add value to the project planning and management process by looking for and delivering savings.

Facility and Project Design Review

GPN SME's are expert in undertaking independent detailed design reviews and can lead

teams through this critical process. Our expertise is based on our direct operational experience in the Pharma Industry and on our experience in designing and reviewing pharmaceutical plant operations. We seek to maintain our knowledge of current regulations and regulatory authorities current thinking on the future. Our approach to design reviews is to look at the facility or site from a manufacturing, supply chain and compliance view point to ensure that the engineering solutions in the design align themselves with the requirements of the client's staff, and those of a modern manufacturing and supply organisation. This ensures that the material/process flows, regulatory compliance, safety, cost, and technology proposed are considered and the impact on the integrated project timelines assessed.

Project Management

All GPN SME's are proficient in the planning, managing, and execution of key business projects. Our SME's have been involved in the planning and managing of multi-million dollar projects. These projects have included full site design and development, process design, business process re-engineering, new product/ market introduction, compliance evaluation upgrades, and both equipment, process and computer systems qualification

Strategy Development

Developing a strategic plan is vital for both a site, a division and a corporation. It provides the vision and leadership for the development and success of the organisation. GPN's SME's have the skills and experience to help develop your facility and/or corporate strategy. The strategy will define the direction and roadmap for the next five years and identify incremental goals and objectives that facilitates the achievement of those goals. This strategy document provides direction on site and facilities development, products to be made and those to be discontinued and sold off, technologies to be used in the future,



capital expenditure budgets, quality systems and standards, manufacturing systems and standards, supply chain strategy, IT strategy, etc

Supply Chain Operations

GPN have experience across the complete Supply Chain from developing of the global supply chain strategy, to the developing and managing customer relationships, through manufacturing, to partnered supply from vendors. Our Supply Chain SME's have worked within materials, purchasing, manufacturing and distribution. In addition to direct experience of managing multi million dollar supply lines our team is expert in the application of modern supply chain systems. By merging the application of the ERP and Shop Floor Control systems with the supply chain processes our SME's can leverage improved customer service, streamlined manufacturing cycles and optimised inventory levels on site.

Quality Systems Development

Quality Systems are integral and vital to the successful operation of a pharmaceutical manufacturing site. We can assist in the evaluation, modification, and transfer of quality systems from the parent operations (if this applies), and in the development and implementation of new systems. We can facilitate the system design discussions that will be of benefit in ensuring that the direction of the work is the best possible to ensure that the business and regulatory needs are met. When a new operation is considered it is always a chance to develop the best systems based on experience and ensuring that the changing business and regulatory environment are taken in to account.

Regulatory Compliance and Quality Auditing

The Regulatory framework is constantly changing and it is important to get current information and a view on the emerging trends. GPN experts keep themselves up to date on these changes and issues through

participation in seminars, notifications, etc. It is useful to have an independent view on a company's operations on a regular basis to ensure compliance and to highlight areas for improvement.

The advantage of choosing the GPN auditing group to do this is that:

GPN see many more companies operations and you get can benefit from this experience GPN have professional auditors with industry experience and know where to look for issues

GPN can assist in identification of improvement ideas

GPN can implement improvement ideas also GPN experts have views on the industry trends

GPN are not constrained by internal company constraints

Operational Improvement

GPN SME's have a large amount of experience in managing pharmaceutical operations. This experience has been obtained from working in senior operations management positions in some of the worlds leading Pharma Companies. We can use our skill and experience to support the existing operation by reviewing the existing facility operations and management practices and then providing direct support to the key daily operations. Depending on the status of the operations this support can be provided in different ways. Where an operation is not currently successful our SME's can leverage their experience to turn around poorly performing areas either by supporting the existing team and management or by providing direct leadership to the team. Where an operation is performing but needs to understand how well it could perform our SME's can support the team in the assessment of it's performance through benchmarking and gap analysis to identify the risks, issues and opportunities available to them. Improvements may be required in quality, capacity improvement, capital productivity, inventory usage, cost

3 pronged approach to business improvement

- Use our knowledge to resolve the issues or develop new processes and ideas
- Teach the client team's how to do this for themselves - prevention of knowledge drain
- Automate the process where possible - long term prevention of knowledge drain



reduction, etc. This may be a large step change process improvement or a series of small changes. An improvement scheme would be defined with defined targets and a plan for how to achieve it. We would then implement the plan e.g. using Lean Manufacturing technology. Various tools could be used during the investigation or problem resolution phases. A measurement system would be installed. See also Continuous Improvement

Continuous Improvement

GPN has 20 years experience in the implementation and management of continuous improvement projects and programmes on client sites. GPN SME's make use of site resources and teams to get client engagement in the continuous improvement process. In this way the site personnel develop ownership of the CI process and the skill and expertise to sustain the process on an ongoing basis. As part of this process GPN can supply training in the standard analytical tools commonly used to drive the continuous improvement process. This is the ongoing process of continually upgrading your operations. We could audit the existing facility operations and compare it to best practice. A gap analysis will identify risk, issues and opportunities. Improvements may be required in any area e.g. quality, capacity improvement, capital productivity, inventory usage, cost reduction, etc. An improvement scheme would be defined with clear targets and a plan for how to achieve it. We would then implement the plan using proven techniques e.g. Lean Manufacturing technology. Various tools could be used during the investigation or problem resolution phases e.g. Brainstorming, Force Field analysis, Pareto analysis, SMED, Kepner Trego, Cause and Effect, Story boards, etc.

Technology Transfer

GPN can design the technology transfer management framework. Technology transfer

management is a key discipline to the successful start up and ongoing operation of a facility. It provides the basis for the quality of the product, the robustness of processes, the stability of supply and facilitates the education of the workforce. With our expertise we can plan and implement a multi-disciplined process to new product and process introductions that ensures a robust start up and ensure that the training and education plans of the personnel on site are aligned with all of the technical requirements. This critical area requires high calibre resources that are competent on the products and processes that are being transferred. In addition to understanding the processes GPN SME's are skilled in both problem solving and project management methodologies and as such can provide a more effective and streamlined approach to the transfer.

Product Development and Problem Solving

Problems do occur in plants. We can investigate and help resolve product and process problems particularly for those nagging problems that do pop up from time to time. Particular areas of expertise are powder handling, tablet technology, process improvement and quality related issues. It is very useful to resolve issues before technology transfer to a new plant to prevent escalation of the issues. The methodologies used will depend on the problem found and may incorporate some of those mentioned already of Brainstorming, Force Field analysis, Pareto analysis, SMED, Kepner Trego, Isikawa and Cause and Effect, Story boards, etc. Statistical analysis of data is important in this process also.

Learning, Education & Team Development

GPN's strategy is for a 3-pronged approach to the challenges of an organisation. This approach can be summarised as



USE our knowledge to resolve your issues and meet your challenges,
TEACH the organisation the tools and techniques needed to continue this work on their own
AUTOMATE/EMBED and integrate the tools and techniques into the site systems so that the knowledge drain is minimised.
Implicit in this strategy is the recognition that it is essential for an organisation to learn and develop in order to achieve world-class operations. In keeping with this GPN SME's keep teamwork and development at the forefront of all assignments. We do this in two ways. Firstly, our SME's work with the organisation teams to impart the practical expertise to the team and secondly we provide a range of classroom courses through our training SME's to teach the organisation the tools and skills that may be required to achieve their goals. This combination of theory and mentoring provides real support and aids the development of a team-based culture. It also facilitates passing on the knowledge from our consultants to the client's staff and is of significant long-term value.

Organisational Design

An integral part of the development of a new site, the introduction of a new product or process or the re-engineering of an existing business is the development of the organisation itself. GPN has worked directly in the industry and we have direct experience of the various cultures and styles that have been developed over the years. Based on this experience we can advise on the most appropriate organisational structures in terms of headcount, reporting relationships, management systems, employee involvement and collaboration. In addition to this GPN has many links and associations within the 3rd level college community. Once the organisation has been defined GPN can use

it's experience and network of associated companies to identify the most suitable methods of sourcing appropriate candidates for positions

System Application

GPN has a wide amount of skills and expertise in the design, configuration and implementation of all key business systems ranging from, ERP, LIMS, KPI reporting, Document Management Systems, Knowledge Management Systems, Bar Code Data Collection Systems and MES systems. A key challenge in implementing systems is in selecting systems that add value to the processes on site as opposed to implementing software functionality. GPN take a process orientated approach starting with the identification of actual business processes on site, review of functionality and then agree on optimised processes which are leveraged off the functionality available.

Automation

GPN automation SME's have in excess of 12 years experience in the design, development and implementation of process automation systems in the Pharma Industry. Our SME's ensure that the strategic issues with automation are addressed as part of all assignments. Such issues include standardisation of systems and infrastructure, common methodology of design and qualification between all vendors. In addition all our SME's are fully versant in the requirements of GAMP4 and 21CFR Part 11 and EU Annex 11 and are capable of undertaking compliance reviews on behalf of clients.