Leading Global Serialization Programs

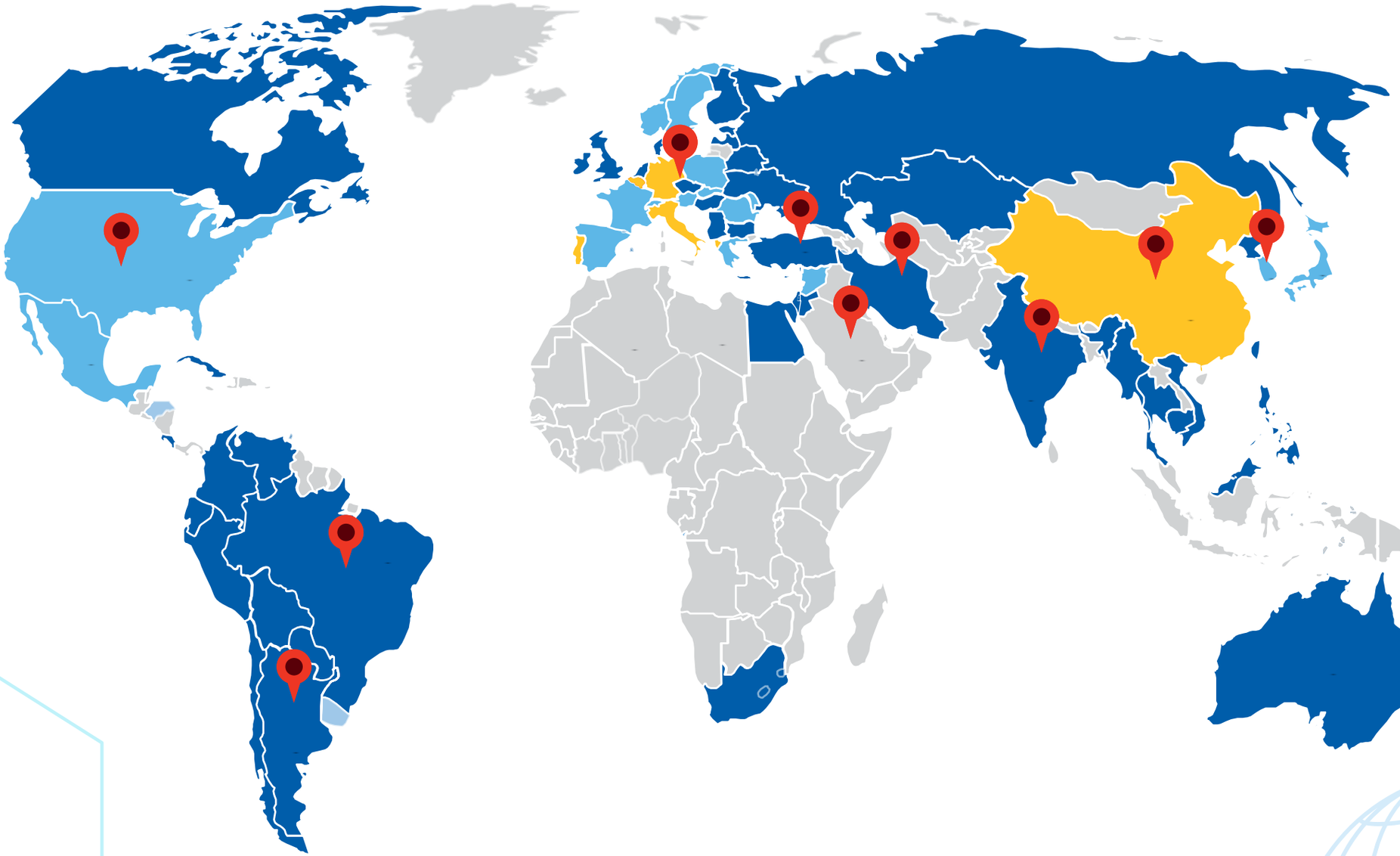
Many nations have enacted serialization regulations to combat counterfeit products and diversions of legitimate pharmaceutical products, and those that have not are planning to do so. Despite the standards outlined by GS1, these regulations may have varying requirements. For instance, while unique serial numbers are required on the saleable unit packages in all countries, the United States strongly implies the need for aggregation.[1] Most countries allow unit saleable package serial numbers to be combined with product Global Trade Identification Numbers (GTINs), but Brazil requires them to be unique across all GTINs. Some countries require randomization of unit saleable package serial numbers, though these requirements are not standardized. Furthermore, the national government of China provides serial numbers to manufacturers.

Pharmaceutical companies that operate or distribute their products on a global scale must be aware of these differences – along with the deadlines for such requirements.

Leading Global Serialization Programs

- Accepts GTIN
- Requires NTIN
- Requires National ID #
- Specific Country Requirements

Click on these icons to view specific requirements for designated countries.



Global Serialization Regulations

HARDWARE & SOFTWARE VENDORS

Vendors providing essential computer software & hardware for serializing packaging lines (L1, L2, L3 systems) are under intense pressure to meet demand. As such, many are rapidly expanding their workforces; however, new employees are often less efficient, which may impact lead and response times. Equipment fabrication and delivery lead times are also increasing, often by between 50 and 100%.

PARTNER COMPLIANCE REQUIREMENTS

The US deadline for serialization by all manufacturers is November 27, 2017. Many companies have begun implementing serialization solutions. Some trading partners, including the largest pharmaceutical distributors, are requiring serialization with aggregation well in advance of the regulatory deadline to optimize business efficiency. More will do so as the deadline approaches.

LABELING & PACKAGING DESIGN

Artwork considerations must be addressed in advance of, and throughout, equipment installations. Current unit saleable packaging designs may not accommodate the 2D or human readable serial numbers. Redesigns typically include revising layouts, font sizes, and colors to ensure sufficient contrast and clarity for scanning.

PRODUCTION FACILITIES & CAPABILITIES

Since most packaging lines were not designed with serialization in mind, installations often require relocating, modifying, or replacing equipment, and perhaps alterations to plant buildings and infrastructure. In addition, to meet demand, packaging lines may not be available at optimal times for serialization installations and testing.

SERIALIZATION RESOURCES

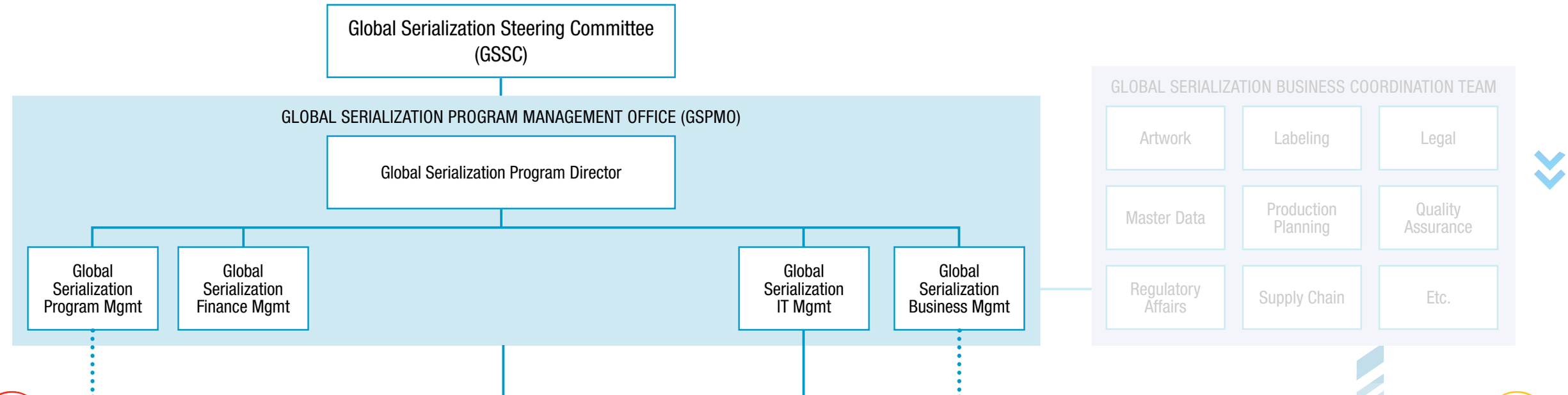
Ensuring that the appropriate resources are available to lead, manage and implement serialization initiatives is critical. While leadership support is vital to the success of any such project, global serialization will also require input and collaboration from departments across the organization.

Additional Considerations

Global Serialization Program Management & Steering Committee

Pharmaceutical serialization requires a global approach. Based on our experience working with some of the world's leading pharmaceutical companies, we have built a program management approach that provides business guidance, governance, budget oversight and project coordination on a global, corporate level. Serialization implementations are then managed locally in alignment with the global program.

The Global Serialization Steering Committee (GSSC) is composed of senior executives representing the business as a whole. The committee meets periodically to review reports on serialization progress and to provide overall business direction. It establishes the corporate budget for serialization and authorizes the release of funds from the serialization budget for individual serialization projects.



Global Serialization Program Management Office

WITHIN THE GSPMO

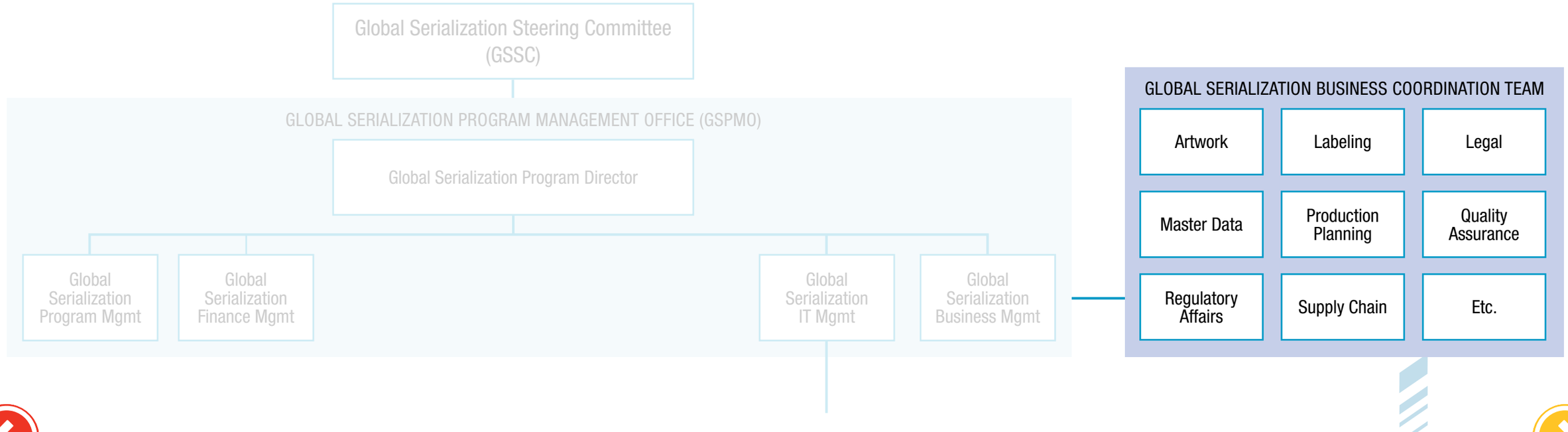
Global Serialization Program Director: This pharmaceutical company executive leads the GSPMO and is responsible for imparting the GSSC's directions to the individual serialization projects. He/she is assisted by Global Serialization Program Management.

Global Serialization Program Management: This function (1) leads coordination between the GSPMO and the individual serialization project steering committees, (2) provides guidance to the individual project managers to ensure synchronization across projects, (3) prepares the status reports for the GSSC, and (4) is responsible for GSPMO administration.

Global Serialization Finance Management: This function establishes the budget and guidelines, and monitors the project steering teams and project managers.

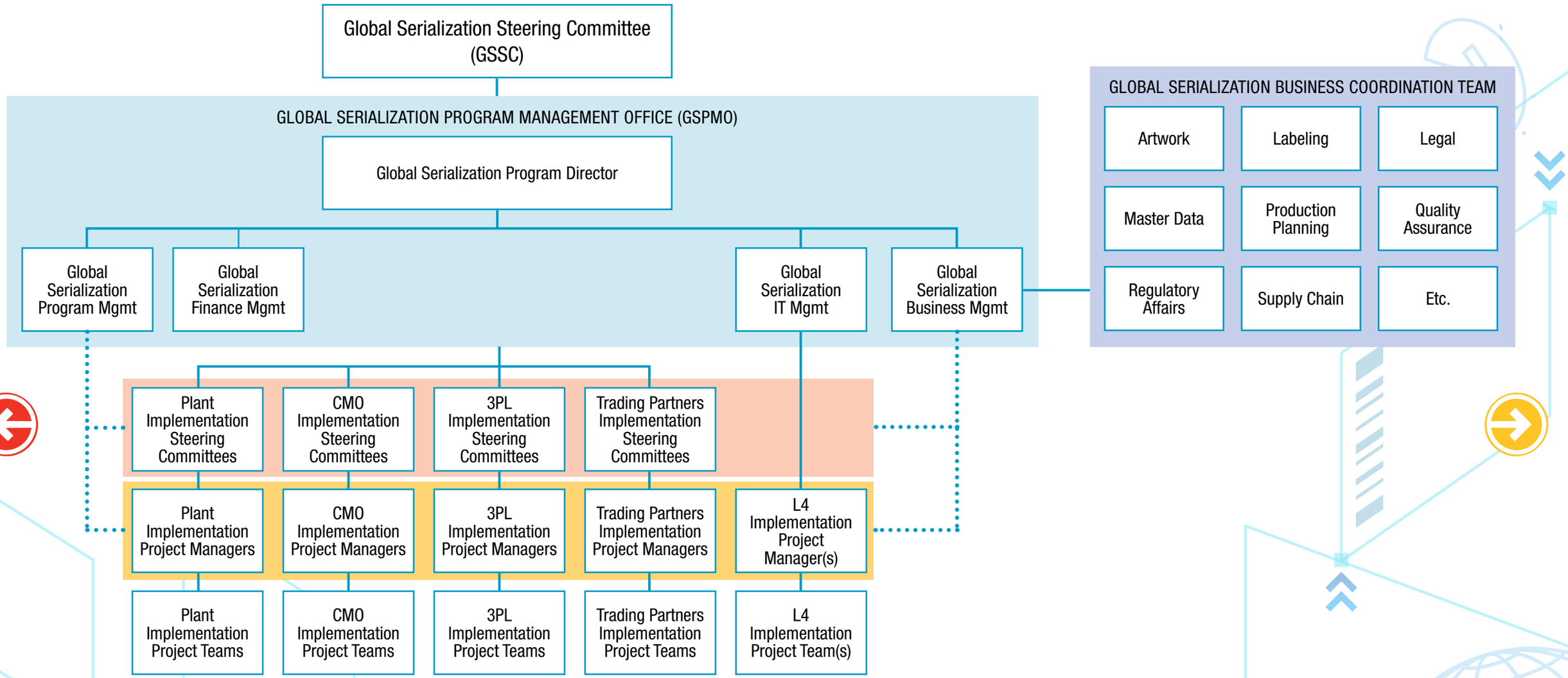
Global Serialization IT Management: This function provides systems guidance and coordination to the IT leaders on each serialization implementation project and executive direction to the L4 implementation project(s).

Global Serialization Business Management: This particularly important function provides overall business guidance to the program. It provides recommendations to the GSSC and direction to the Global Business Coordination Team, outlined next.



Global Serialization Business Coordination Team

This multidisciplinary team forms the bridge between the global serialization program and ongoing business practices. During the global serialization program, its members work with the various serialization project teams to schedule product artwork, labeling, production scheduling, regulatory filings, and other work mandated to meet serialization regulatory and business requirements. As the program nears its end, these team members build on the knowledge gained through the program to manage serialization within daily business operations.



Global Serialization Project Teams

Serialization equipment and systems implementation and testing is performed by multiple project teams in accordance with overall program governance provided by the GSPMO.

About the Authors

Don Eberts is a senior manager with Clarkston Consulting. He has over 45 years of experience in the fields of international program management, project management, process analysis, and engineering design and management. He has managed multinational programs and individual projects in Australia, Belgium, Germany, Ireland, Japan, and the United States. Mr. Eberts is currently serving as program manager for a client implementing a global serialization program consisting of simultaneous multi-phase projects in Ireland, the Netherlands, Japan, and the United States.

David Treadaway is a senior manager with Clarkston Consulting. He has over 25 years of information systems experience in the consumer products, pharmaceutical, medical device, and high tech industries. For the last three years, Mr. Treadaway has managed serialization and track & trace projects involving pharmaceutical anti-counterfeiting efforts and regulatory compliance for the United States and European Union. Mr. Treadaway is also working with several clients to design and develop their serialization strategies, preparing them for compliance with worldwide serialization regulations. He and his team also developed a serialization training course for both Clarkston stewards and their clients.

- For more information about US DSCSA, read our latest Insights Paper. »
- Read about how we helped a global pharmaceutical company develop and implement their serialization pilot program. »
- To learn more about our serialization and track & trace solutions, download our Solution Overview. »

About Clarkston Consulting

Clarkston Consulting provides management and technology consulting services for life sciences and consumer products companies. Clarkston has achieved a 12-year average client satisfaction rate of 97% by continuously pushing for success for our clients, our consultants, and our company.

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