The CIMdata Medical Devices Action Group

Defining Best Practices for Improving Compliance while Accelerating Product Development for Medical Device Companies

Every medical device company wants to get to market faster to benefit from the first-mover advantage. On the road to commercialization, not everything is within the company's control. Needless to say, regulatory bodies around the world hold companies accountable to standards and requirements that are getting tougher by the day. All medical device manufacturers have to balance speed to get to regulatory submission and commercialization with the need for regulatory compliance. Regulatory compliance requires "production" and "assembly" of a significant amount of data and documentation during the entire lifecycle of the product. Production and assembly of data take time, effort, and resources, adding cost and extending timelines.

While subject matter experts engaged in the development of new products, features, and functionality are mindful of compliance requirements, they are typically not excited about producing documentation for compliance. So, how do we make the production and assembly of documentation for compliance during product development, manufacturing, distribution, and maintenance less onerous on resources, and free up their time to do even more creative work so they can develop even more lifesaving products and improve patients' quality of life? In other words, how can we automate the production and assembly of documents and data for compliance as an effortless by-product of product and process development and manufacturing? The concepts of "digital twin" and "digital thread" can be applied and leveraged to accomplish this which not only makes it less onerous on resources, but also enables reuse of data and documentation for the next generation and next iteration product development—thereby accelerating product development.

CIMdata's Medical Devices Action Group (MDAG) brings together subject matter experts from member companies who will direct and oversee the definition of best practices for how information systems, specifically, PLM/PDM solutions can be leveraged for managing product data from concept through regulatory compliance to commercialization and beyond. Under the guidance and governance of members of the MDAG, CIMdata's consultants (including individuals with extensive expertise in medical devices as well as other similar industries and expertise in PLM enabling solutions and processes) will work to define the processes, data models, best practices, and system requirements to support effective and efficient product lifecycle management, and work with solution providers on behalf of the MDAG member companies to provide validated requirements for development of the features and functionalities that are needed by the medical devices industry.

The MDAG provides a unique opportunity for medical device companies to maximize the benefits they receive from their PLM related investments.

Enrollment is open to major medical device and life science equipment companies who wish to collectively address PLM-related challenges, close technology gaps, expose needed standards, and co-sponsor collaborative research with CIMdata.

Participation in the Action Group enables members to make more informed business decisions by providing timely and valuable information, insights, and advice, while networking with companies with similar PLM challenges. Through connections within the CIMdata Community there is also exposure to best practices of organizations outside the medical device industry that may confront similar challenges.

Participation in the Action Group facilitates an on-going working relationship with CIMdata that strengthens and enhances the value of support available to your organization from CIMdata and from the industry at large including solution providers, systems integrators, and other related technology (e.g., additive manufacturing) and service providers (e.g., cloud).

The CIMdata Medical Devices Action Group provides the opportunity for members to participate in facilitated collaborative discussions and problem-solving sessions with industry peers. Additionally, members will drive the prioritization of research and analysis to define current PLM best practices, insights, and lessons-learned for medical device companies in topics such as:

- The reality of the real-time product record (the digital twin) driving concurrent compliance and quality documentation, e.g., DHF, DMR, and DHR.
- The level of risk in maintaining information silos, e.g., best practices and strategies for managing and ultimately integrating PLM with QMS, ERP, MES, and other enterprise systems, including definition of information ownership and boundaries of each system.

In summary, participation in CIMdata's Medical Devices Action Group provides:

- Access to on-going research, analyses, insights, and advice.
- Participation in the identification and prioritization of the top industry-specific PLM topic areas that will direct related CIMdata research.
- Current information on PLM industry news and trends.
- Access to CIMdata's PLM subject matter experts (SMEs).
- An interactive and collaborative environment for accessing and sharing PLM-related processes and technology-oriented best practices.
- Other benefits from participating in the global CIMdata Community, an active group that includes both leading industrial companies and providers of PLM solutions from around the world.
- Admission to CIMdata's PLM Certificate programs at reduced rates.

Participation in CIMdata's Medical Devices Action Group is an annual fee-based membership. Membership provides access to the following deliverables:

Generalized Deliverables Include:

- ***Access to Industry Relevant Best Practice Research***—Group members can define, prioritize, and participate in current and relevant best practice research for PLM in the medical device manufacturing industry, facilitated and driven by CIMdata. Research topics can be submitted for consideration by all Action Group members.
- ***Active Participation in CIMdata's Community***—Members actively participate in CIMdata's on-line Community communications including a CIMdata industry blog as well as off-line interaction with CIMdata personnel.
- ***CIMdata Research Reports***—Members receive copies and updates of selected PLM industry research reports from other CIMdata supported groups. These include copies of:
- The *CIMdata Executive PLM Market Report*—This report provides summary information and analysis of the worldwide PLM market. Alternatively, members can receive a discount on the full five-volume Market Analysis Report Series.
- On-going research reports—Periodic research reports that address timely and major issues and trends within the PLM industry.
- CIMdata whitepapers and eBooks—Members receive advance copies of all position papers and whitepapers, and eBooks that CIMdata publishes during the year.
- Discounts on other CIMdata research publications—Special member-only rates on other CIMdata research publications.
- ***CIMdata PLM Certificate Program Discounts***—The CIMdata PLM Certificate program is a well-defined, assessment-based PLM education offerings for industrial companies and PLM technology and service solution providers. You enjoy special member-only rates whenever one of your employees attends a CIMdata PLM Certificate program.
- ***Bi-Monthly Meetings***—The Action Group meets at least six times per year, either in person or through conference calls. Exact timing is determined by the Action Group members.
- ***Scheduled Action Group Web-Based Forums—***An example of this is the delivery, discussion, and summary of specific CIMdata research and their potential impact for PLM in medical devices.
- ***Action Group Annual Meeting***—the Action Group will hold an annual meeting at a location determined by the Action Group members.
- ***PLM Late-Breaking News***—A daily electronic newsletter that provides up-to-the-minute information on PLM market activities, products, events, sales announcements, and PLM solution provider activities along with CIMdata comments on key events.
- ***Weekly PLM Industry Summary***—A compilation of news and announcements provided in the daily PLM Late-Breaking News. Published weekly, it serves as an abridged reference for major developments in the PLM industry.
- ***Position Statements***—Concise reports summarizing CIMdata's expert analysis of the issues, trends, technologies, and events taking place in the PLM marketplace, with comments on their impact for end users and the industry.

Personalized Deliverables Include:

- ***Annual Strategy Session***—During this two-day session (to occur within the membership year), your team and executives will meet privately with CIMdata consultants to provide a review of your programs and discuss PLM strategies or any other PLM-related subjects that are considered of importance to your team. This is an excellent opportunity for your team to discuss strategies and issues, and receive appropriate feedback and recommendations. *The session is to be scheduled at your facility at a mutually agreed time and all travel expenses are to be covered by the member.*
- ***CIMdata PLM Road Map Participation***—One registration to any of CIMdata's PLM Road Map™ conferences. PLM Road Map is a strategic conference focused on how companies are successfully employing PLM strategies and enabling solutions to meet challenging product development, manufacturing, and deployment issues.
- ***CIMdata PLM Resource Support Line***—Provides personal access to CIMdata's consultants and their expertise. Your Named Users have access to CIMdata's

subject matter experts to discuss issues and questions as they occur during the year. This support includes brief telephone and email discussions of topics, but does not include support to conduct additional research.

- ***Three Named Users***—Contacts who receive direct mailing of the Late-Breaking News and other publications and reports. These individuals are also your points of contact to CIMdata's PLM Resource Support Line for information and research on the PLM industry and market. Additional Named Users may be added for a fee.
- ***Corporate License***—You receive a corporate license to distribute CIMdata provided news and authorized reports throughout your organization for internal use. Named Users may forward or post these materials to colleagues within your company. If you choose, CIMdata will directly email news to multiple individuals within your team.

Membership in the CIMdata Medical Devices Action Group Costs US$25,000/Year

About CIMdata

CIMdata, an independent worldwide firm, provides strategic management consulting to maximize an enterprise's ability to design, deliver, and support innovative products and services by identifying and implementing appropriate digital initiatives. For nearly forty years, CIMdata has provided industrial organizations and providers of technologies and services with world-class knowledge, expertise, and best-practice methods on a broad set of product lifecycle management (PLM) solutions and the digital transformation they enable. CIMdata also offers research, subscription services, publications, and education through certificate programs and international conferences. To learn more, visit www.CIMdata.com or email info@CIMdata.com.