

Siemens Digital Industries Software

Accelerating growth for emerging medical device and diagnostic industry SMB manufacturers

Unique challenges MD&D presents for SMB manufacturers





Emerging medical device and diagnostic (MD&D) companies have a relatively smaller group of process, engineering and IT resources to implement, deploy and maintain their hardware and software infrastructure.

Less-experienced users and fewer support staff



Typical within the small-tomidsized business (SMB) manufacturer is a workforce of less-experienced operators and fewer dedicated IT support resources.

Speed in the compliance process



While regulatory approval can make or break an SMB manufacturer, their compliance processes are typically less mature than their larger competitors.

Acceleration of growth



Emerging MD&D manufacturers must have innovation efficiency to compete with large industry incumbents.

The role of manufacturing operations management

Five key capabilities of manufacturing operations management (MOM) for SMB manufacturers



Orchestration

MOM provides the orchestration and planning of manufacturing and quality operations.



ERP integration

MOM bridges the gap between enterprise resource planning (ERP) integration.



eDHR/eBR

MOM automatically generates the electronic device history record/ electronic batch records (eDHR/eBR), supporting more rapid compliance processes.



Paperless manufacturing (eDHR)

better controls and reduces the total cost of goods sold (COGS).



Visibility

MOM transforms big data into IoT smart data and provides the intelligence for improvement and innovation.

Required digital infrastructure for growth of SMB companies in MD&D

Standard, pre-configured modules: The pre-packaged software configuration that provides the core MOM functionality critical for the SMB



An accelerated implementation and validation approach created specifically for MD&D manufacturers



Cloud support and maintenance: The option to use Siemens' infrastructure and/or managed services



Stepwise approach for the MD&D industry for SMB manufacturers

Opcenter Execution (EX) for Medical Device and Diagnostics (MDD) Rapid Implementation Package

- Preconfigurations
- Implementation of out-of-the-box (OOTB) features only
- Risk-based approach to validation

Addressing the delta

- Integration to third party business systems
- Custom reports

Continuous improvement and extensions

 Possibility to scale-out the solution by leveraging the Opcenter portfolio as well as Siemens Digital **Industries Software**

For more information, visit siemens.com/medicaldevice