PTC WINDCHILL & BYRD HEALTH **FAQ**

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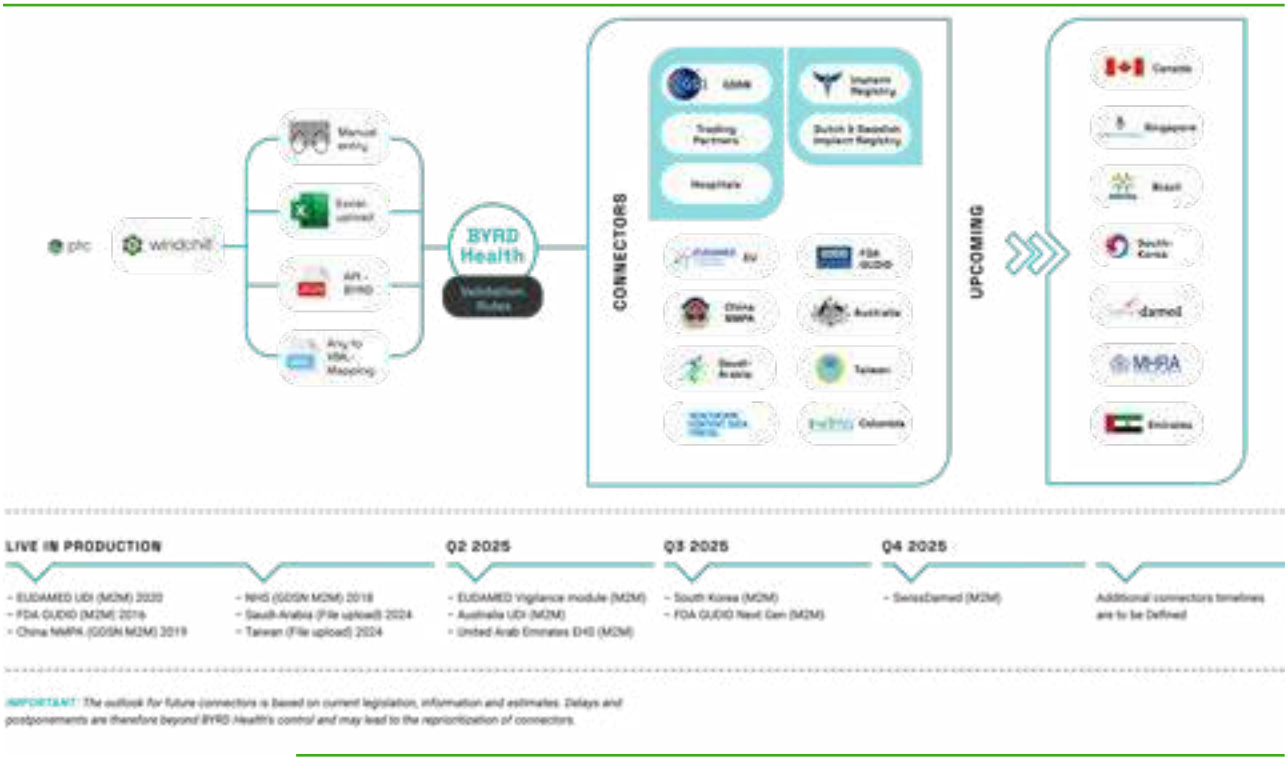
Why Have PTC and BYRD Health Partnered?

PTC Windchill Med Dev is a Medical Device PLM. It is your central hub for product information about the medical devices you develop. PTC's MedTech customers use Windchill Med Dev as integral part of their regulatory submission processes.

Windchill accommodates the device data for Federal Regulatory Requirements (European Commission EUDAMED, US FDA UDI/GUDID, Australia TGA, Saudi Arabia SFDA, etc.).

Each of these countries/entities vary in the data elements required, the format data is to be sent in (XML, SPLR7, .csv,,,,) M2M (Machine to Machine) and the protocol (AS/2, AS/4 etc.) required for the transmission of the data.

BYRD Health provides the connectivity to Regulatory databases and is the leader in this area. Thus, PTC and BYRD Health work together to provide the optimal model for the creation, maintenance and syndication of medical device product master data. See Diagram Below.



What is EUDAMED?

EUDAMED is the European Database on Medical Devices, designed to improve transparency and coordination of information regarding medical devices available in the EU market.

1. What are the main modules of EUDAMED?

EUDAMED consists of six modules:

- Actor Registration
- UDI/Devices Registration (This is the module PTC and BYRD help with. You can maintain all of the required information in PTC Windchill and see registration status in Windchill. Windchill communicates this data to BYRD Health via JSON and BYRD Syndicates to EUDAMED, Reporting Statuses back in Windchill.

- Notified Bodies and Certificates
- Clinical Investigations and Performance Studies
- Market Surveillance
- Post-Market Surveillance & Vigilance

2. Who needs to register in EUDAMED?

Manufacturers, authorized representatives, importers, and system/procedure pack producers within the EU must register. Non-EU manufacturers must have an authorized representative within the EU.

3. Is EUDAMED mandatory?

Yes, EUDAMED is a key component of Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR), ensuring compliance with EU medical device regulations.

4. Where can I find official guidance on EUDAMED?

The EUDAMED Information Centre provides official documentation, FAQs, and user guides here: https://webgate.ec.europa.eu/eudamed-play-help/en/welcome-to-the-eudamed-information-centre.html

US FDA Unique Device Identification (UDI)

1. What is UDI?

UDI (Unique Device Identification) is a system that assigns a unique identifier to medical devices to enhance traceability, improve patient safety, and reduce medical errors. Official USA FDA Reference: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system

2. What is the GUDID?

The Global Unique Device Identification Database (GUDID) is a database administered by the Food and Drug Administration (FDA) that contains information about medical devices with unique device identifiers (UDIs). It's a centralized repository for tracking and identifying medical devices, helping to ensure traceability and facilitate post-market surveillance.

Key points about GUDID:

- Centralized Repository:
  - The GUDID is a central database for medical device information, maintained by the FDA.
- UDI Link:
  - It links each device's UDI to a specific set of information about that device.
- Traceability:
  - GUDID facilitates traceability by providing a detailed record of each device, including its manufacturer, intended use, and other relevant details.
- Post-Market Surveillance:
  - The database supports post-market surveillance, allowing the FDA to track and monitor devices in the market.

- Publicly Accessible:
  - The GUDID data is publicly accessible through a web portal called AccessGUDID.
- Regulatory Requirement:
  - The GUDID is a key part of the FDA's UDI system, which is a regulatory requirement for medical device manufacturers.

3. Why is UDI important?

UDI helps in:

- Tracking medical devices throughout their lifecycle.
- Enhancing post-market surveillance.
- Reducing counterfeit devices.
- Improving inventory management in healthcare institutions.

4. How do I register UDI information to the US FDA?

Products must be entered to the GUDID. This is Mandatory. This is the database for the US FDA of medical devices. (This is the module PTC and BYRD help with). You can maintain all of the required information in PTC Windchill and see registration status in Windchill. Windchill communicates this data to BYRD Health vias JSON and BYRD Syndicates to EUDAMED, Reporting Statuses back in Windchill.

What Other Countries/Markets are Introducing UDI Requirements/Regulations

Who do I contact with questions or to set a meeting?

Contact PTC for questions and more clarification.

At osapiens for Medical Devices (BYRD Health) contact Jeff Holzman