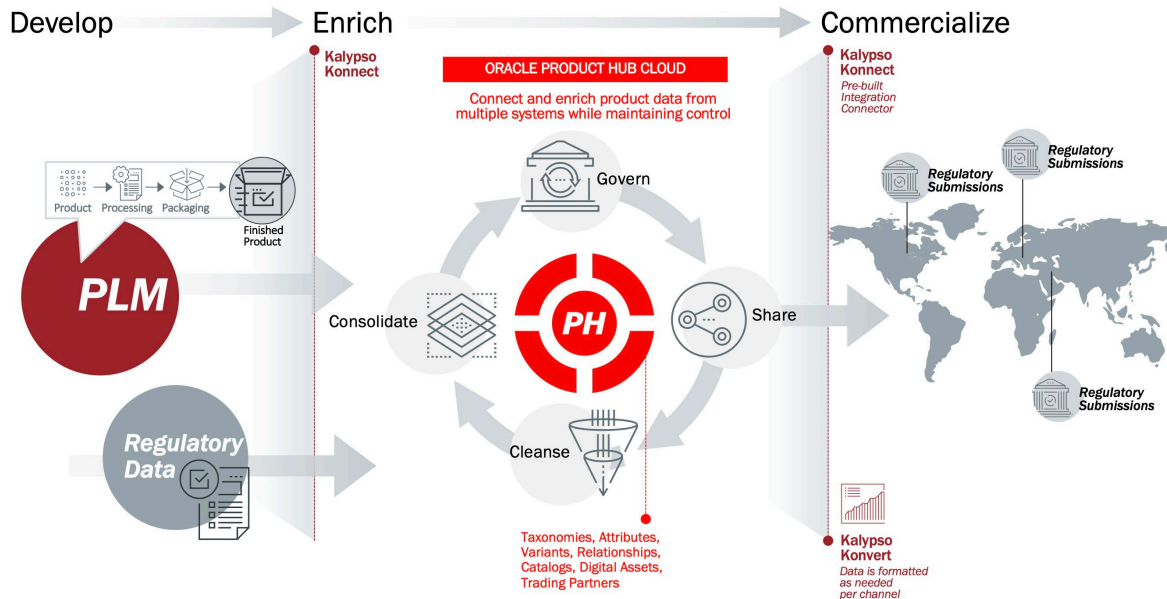# Regulatory Submission Enablement and Optimization

Consistently and efficiently collect, categorize and transmit product information to regulatory agencies in different jurisdictions **with Oracle Product Hub Cloud**



**Develop** → **Enrich** → **Commercialize**

Kalypso Konnect

**ORACLE PRODUCT HUB CLOUD**
Connect and enrich product data from multiple systems while maintaining control

Govern

PLM

Consolidate

PH

Share

Cleanse

Taxonomies, Attributes, Variants, Relationships, Catalogs, Digital Assets, Trading Partners

Regulatory Data

Kalypso Konnect
*Pre-built Integration Connector*

Regulatory Submissions

Regulatory Submissions

Regulatory Submissions

Kalypso Konvert
*Data is formatted as needed per channel*

## Benefits

- Improved governance of regulatory submissions
- Faster time-to-market for initial product launch and product variations
- Reduced data management costs and transactional errors
- Improved abilities to capitalize on market opportunities in different geographies
- Reduced regulatory penalties and compliance costs

**Excel in regulatory submission management** with a low-risk, low-cost implementation of Oracle Product Hub Cloud enabled by Kalypso expertise

- ✓ Industry-leading commercialization practices in consumer goods, life sciences, manufacturing
- ✓ Managed services for regulatory submission templates
- ✓ Deployment experience in hybrid (cloud/on-premises) and all-cloud environments
- ✓ Broad integration competency (PLM to authoring tools, ERP, PPM, CPQ, QMS, manufacturing applications, etc.)
- ✓ Proprietary pre-built integration connectors

# Remove the **Burden** and **Risk**
# of Regulatory Compliance Management

Businesses in regulated industries such as food and beverage, pharmaceuticals, biotechnology, medical devices and others must comply with an increasing number and frequently-changing guidelines and restrictions that vary by region. This is a cumbersome and overwhelming task impeding speed-to-market abilities while maintaining compliance. Non-compliance is not an option – it is costly, can be damaging to a brand, and harmful to consumers and patients. Companies are looking for new ways to overcome this growing challenge.

*Do you experience product or product variation launch delays due to regulatory submission inefficiencies?*

*Are you able to consistently and efficiently collect, categorize, aggregate and transmit product information to regulatory agencies in their specified formats?*

*Are you able to quickly respond to changing regulatory requirements?*

## Risks

- Slower time-to-market
- Lack of governance during item enrichment activities
- Ineffective cross-functional collaboration
- Incomplete, inconsistent, erroneous product information being distributed to regulatory agencies
- Revenue losses and fines due to wrongly structured or incomplete compliance data
- High data management cost

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