



## ROBAR—Out-of-the-Box Labeling and UDI Compliance

**Every new challenge inspires innovation and presents opportunity for improvement.**

Innovatum delivers the most complete single source solution for UDI compliance enabling technologies that handles master data management (MDM), GUDID attribute preparation and upload, UDI status reporting, and enterprise label management and printing.

### Label Design and Management

The complete Innovatum solution centrally manages the entire label life cycle—from initial design and review to production use and eventual obsolescence.

It supports compliance with regulations set by the FDA, IMDRF, EU, and individual countries such as China, Turkey, and Brazil. It also enables compliance today and compliance as requirements change over time.

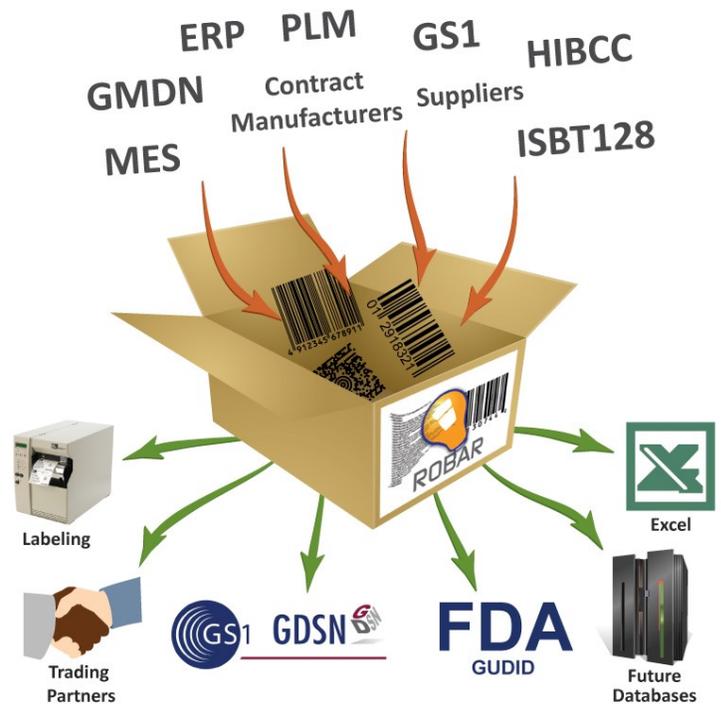
Browser based connectivity allows for local label design to be combined with local, off-site, domestic or international printing. These capabilities can also be used by suppliers outside of your network.

### UDI Compliance

The GS1 certified label design and print engine ensures compliant barcodes. XLS import and existing system data mapping, easily merges any master data to ROBAR MDM.

The scalable, modular ROBAR Communication Manager (COM) ensures flexibility to achieve the functionality that you need today but also provides for future growth.

***Innovatum solutions are designed to keep labeling control in the labeling group, liberating IT for functions that only IT can do.***



### Expect More...

Real-time charting and reporting is only a click away. Dashboards used for the efficient monitoring of MDM updates and change processes allow for unique management of the communication, submission, and acceptance cycle.

The Innovatum UDI solution is available with an integrated ROBAR labeling system or as a simple bolt-on to other systems.

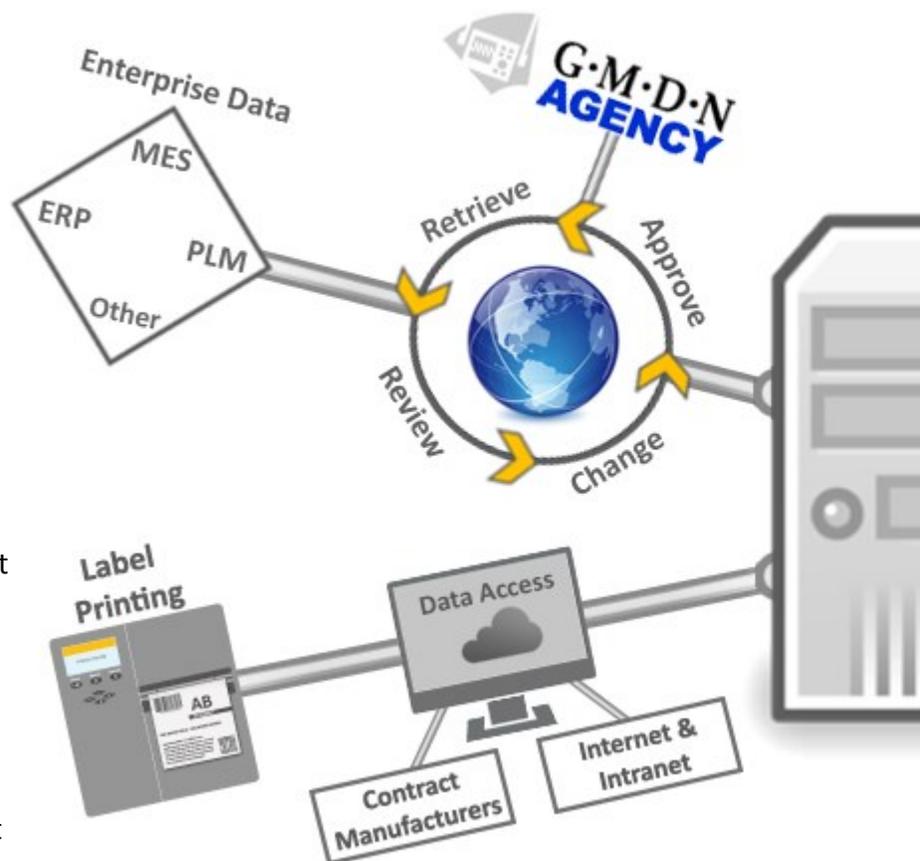
Adherence to life sciences standards is our mission; ROBAR, ROBAR MDM, and ROBAR CM are readily validated, and all appropriate Part 11, 801, and 820 controls are enabled.

# ROBAR Master Data Manager

Decades of experience has taught us that, “single source of truth,” is in actuality multiple sources of truth. Multiple owners have varying levels of permission to access and change data. This complexity is only compounded by multiple businesses, business units, business data owners, contract manufacturers and suppliers, and the need for auditable review, approval, and change management of related data.

**All of this is handled by a multi-enterprise master data management system that:**

- Has a virtually limitless, configurable database established on ORACLE or Microsoft SQL
- Is version controlled with electronic signatures and Part 11 compliance
- Provides one-click access to history of changes for each record
- Supports Excel data import
- Dynamically retrieves data from appropriate ERP, PLM, MES and XML Publishing Systems within the enterprise
- Enforces business unit level and column level security, enabling each department to manage their own data
- Has user configurable drop-down selections, including real-time access to the GMDN for Global Medical Device codes
- Allows entry in HTML or rich text format to support scientific notation, subscript and superscript, branding, and more
- Supports the ability to select multiple entries from a list (i.e., configure kit components or multiple patent numbers)
- Provides immediate and easy access to records in various stages of preparation and submission
- Makes its data available for publication in Excel and documents including, but not limited to labels
- Includes a multi-user, browser based workflow system for review and approval of data
- Presents each user interface in the user’s preferred language



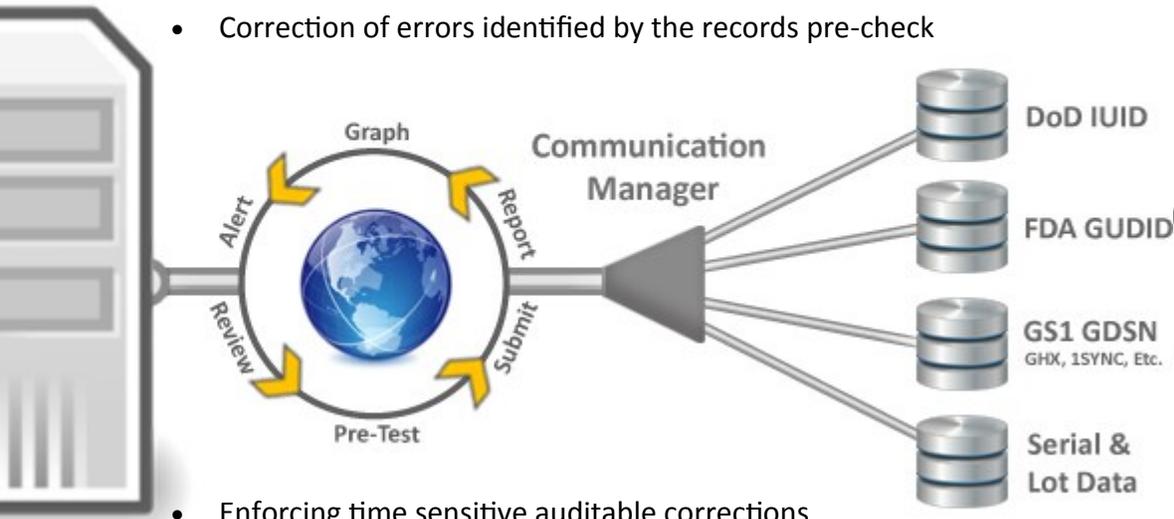
**ROBAR MDM** ships with a completely configured UDI database that contains all required data elements and documented processes for GUDID compliance.

# ROBAR Communication Manager

Once a cleansed and verified repository of data is achieved, any number of external entities can be the recipient of their data segment. Direct upload of UDI information to the GUDID is an out-of-the-box feature of Innovatum's ROBAR Communication Manager. However, companies may want to upload data to GS1's GDSN via one of the data pools, subsequently updating the GUDID. The modular and flexible nature of the ROBAR Communication Manager will allow for a blend of targets for transmitted data. Each additional external data partner such as DoD IUID and the potential FDA SNI database is managed through an individualized plugin built over ROBAR CM.

## **The ROBAR Communication Manager will support:**

- Selecting blocks of records that meet filtering criteria (e.g., internally approved status, family, product name, device class, etc.)
- An easy pre-check of selected records for data accuracy using the FDA's and other algorithms
- Correction of errors identified by the records pre-check



- Enforcing time sensitive auditable corrections
- Communication protocol configuration and data mapping to a target partner's database
- Utilizing HL7, XML, and other methodologies
- Responding to various levels of partner system acknowledgement and error feedback, prompting correction and resubmission
- Approval workflow management, change management, and retention of auditable history to be used for meeting compliance requirements
- Summary and detail reports in PDF format
- New plugins created for future targets such as EU's version of GUDID, custom systems or other

**ROBAR CM** is completely preconfigured for GUDID compliance and will require minimal adjustment after installation.

# About Innovatum, Inc

Innovatum software optimizes the compliant automation of product and package labeling with 24/7/365 support around the world. We tackle tough problems like speeding up label life cycle management, validation, multi-language translation, regulatory icons, PART 11, UDI and serialization through a simple Windows and web based software approach.

## ROBAR Server

The ROBAR server accesses corporate label data stores and can interface with various document management, ERP, and PLM systems. It Uploads templates and label data to the ROBAR Design Stations for label creation, manages quality assurance for approvals, and downloads approved labels and item information to the Print Stations at run time.

## ROBAR Master Data Manager and Communication Manager

ROBAR MDM dynamically retrieves and stores data from appropriate enterprise systems. Additionally, it manages corrections and approvals and makes its data available for publication on all documents including, but not limited to labels.

ROBAR CM filters blocks of records for pre-submission checking, manages corrections and approvals, and submits data verified records to target partner systems like GUDID, GS1 GDSN, DoD IUID, and other systems.

## ROBAR Design Station

The ROBAR Design Station is used by label designers to create barcode labels by accessing data and templates from the ROBAR server. This client-based software allows designers to create and modify label templates, manage the QA approval process, generate sample labels, and create PDFs of labels for quality assurance.

## InnoTasc

ROBAR's integrated browser based workflow module supports label and template approval and routes associated documents while meeting compliance requirements.

## Campaign Manager

Campaign Manager allows users to perform actions on large volumes of data quickly and conveniently. It mitigates redundancy, and conserves time for users while adhering to regulatory requirements.

## Label Reconciliation

Label Reconciliation facilitates the process of accounting for labels following batch printing. It is designed to supplement the printing functionality of the ROBAR label management system, and it provides a means for maintaining traceability of physical labels after the printing process.

## Innoview

InnoView is a report generation tool created to provide users with reports that have been qualified for use. It provides access to pertinent historical records created during label design, approval, and maintenance.

## iROBAR—For IBM i

iROBAR uses best of breed capabilities to combine the legendary reliability and power of the IBM i platform with the infinite flexibility of BarTender, a Windows based design and print engine. No longer does one have to be limited by clunky label design environments and restrictions driven by printer hardware.

## ROBAR Documentation Validation Packet

Innovatum offers a validation packet for ROBAR products, including PDFs of executed validation scripts so that vendor testing activity may be leveraged.

## Our Clients



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