

## Track and Document All Training Records

Omnify Software provides a single, secure location to manage the complete product record including: product data, bill of materials, engineering changes, documentation, project, quality/CAPA, and training records information. The system enhances visibility into the entire product development process by capturing design, manufacturing, quality, service, and customer information and associating it to the product record.

### Automate Internal and External Training Management

The Omnify Empower PLM system offers a Training Management module that provides an automated system to manage all internal and external training events. The Training Management module is integrated with all product and project data stored in Omnify allowing users to associate required training and/or testing directly with events such as:

- New product launches
- Implementation of a product change
- Internal document and process changes
- Machine calibration

By automating the management of training events, the Training Management module enables easy identification of resources who are affected by the event and provides automated alerts for training/re-training and recurring events. This ensures all appropriate parties are notified and guarantees training requirements are fulfilled.

The Training Management Module can monitor changes to items and documents such as standard operating procedures, employee handbooks, policies/guidelines and product revisions. When changes occur to these items, the system can automatically identify users, groups, etc. who require re-training/certification.

A Training Administrator within the Training Management module offers a navigation environment to search who has to be trained on what as well as display due and overdue training. The Training Administrator also provides a mechanism to test comprehension. Tests can be created with grading functionality to determine the level of understanding and requirement for re-testing.

### Satisfy Regulatory Requirements

The Training Monitor assures Regulatory Compliance for manufacturers obligated to meet ISO and/or FDA regulations that require manufacturers to implement and document employee training.

In addition, medical manufacturers required to meet the FDA 21 CFR Part 820 Quality System Regulation must establish procedures for identifying training needs, documenting all training, and ensuring all personnel are adequately trained to perform their designated tasks. The Training Management module combined with the Omnify Quality Management module helps manufacturers adhere to the FDA 21 CFR Part 820 Quality System guidelines.

### Key Benefits:

- Unified location to manage all product, project and training information
- Streamline product rollout processes
- Electronic sign-off and training history records
- Easily identify and alert affected parties
- Comprehension testing
- Ensure all personnel are kept up to date on product and document changes
- Assure regulatory compliance with Quality System requirements



### For More Information:

t: 978-988-3800

e: [info@omnifysoft.com](mailto:info@omnifysoft.com)

w: <http://www.omnifysoft.com>