IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY
Published on *IVT Network* (http://www.ivtnetwork.com)

Validation and Social Media

Joe Zec

By **William Rapp Jan 24, 2013 7:46 am PST**

DEFINITION/CHARACTERISTICS

There is a huge grey area about what actually constitutes social media. However, the following are commonly-mentioned attributes:

- Internet-based applications that allow the creation and exchange of user-generated content
- Ubiquitously accessible (inexpensive, easy to use, timely)
- Interactive dialogue among organizations, communities, and individuals
- Blending of technology and social interaction.

Rough Classifications of Social Media Platforms:

- Collaborative (e.g., Wikipedia)
- Blogs/micro-blogs (e.g., Twitter)
- Content communities (e.g., YouTube)
- Social networking (e.g., Facebook)
- Business networking (e.g., LinkedIn)
- Other (entertainment, games, gambling, etc.)–not generally of interest to life sciences community.

BUSINESS RESPONSIBILITIES

The primary business responsibility is to ensure sponsored sites contain only approved content:

- FDA's view is the rules for products have not changed:
    - Can only advertise approved uses of products
    - No false or misleading claims
    - Fair and balanced benefits versus risks.
- Businesses may have a significant risk that user-contributed content does not comply with content requirements (e.g., may stray into off-label usage, unsupported claims):
    - May need to disable user content (where technically feasible)–thereby removing advantage of "social media"
    - May need to monitor user content: this may necessitate removing or disavowing unapproved user content.

- Businesses may need to monitor user-contributed content for regulated information (e.g., adverse events, complaints).

VALIDATION

The FDA has provided no guidance with regard to validation of Social Media.

A bill entitled "The FDA Safety and Innovations Act" is in Congress that would require some kind of guidance within two years. Exactly what kind of guidance will be provided or how useful it will be is unknown.

It is widely acknowledged that such things as audits or collaboration with social media providers (Facebook, Twitter, etc.) would be a daunting challenge. Therefore, the use of social media sites would likely need to be backed up by other types of controls to ensure trustworthiness and reliability.

These controls would include:

- A process for ensuring that only approved content is uploaded to a company's social media page.
- A process for monitoring user-contributed content and managing inappropriate or regulated information.
    - For example, if a company were to use social media to collect and process complaints, there would have to be secondary mechanisms to ensure that all information is reliably preserved such as copying data to a company-managed database and communicating with customers by other means to ensure that all communications are processed.

SUMMARY

- Predicate rules (e.g., Marketing, Labeling, Complaints) apply to social media as well as traditional media.
- There are currently no requirements for validating social media software.
- Social media will likely be an evolving area where companies will have to be nimble at utilizing for regulated purposes.

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