

# GOVERNMENT & REGULATORY AFFAIRS UPDATE

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2017 Executive Summit

January 27, 2017

## Topics to Cover

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- > Update on Prop 65
  - > SUD Efforts
  - > New Label Requirements
- > Update on UDI
  - > Status of Exemption Request
  - > Prepare for Sept 24, 2018
- > Update on OSHA
  - > Electronic Submission of Injury/Illness Data

# California Proposition 65

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- > SUD Update
  - > Still pending technical review with Cal
  - > Test results very favorable.
  - > Unknown timetable going forward
- > Label and Language Changes
  - > More restrictive
  - > Includes symbols and different warning language
  - > No later than August 30, 2018
  - > Update guidance document

# Update on Unique Device Identifier

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- > **September 24, 2018 for Class I devices**
  - > Existing inventory gets three year exemption
- > **UDI or UPC**
  - > UPC ok for Class I medical devices
  - > UDI issuing agencies
- > **GUDID reporting**
  - > Web interface vs. XML file via HL7 SPI
  - > Set up and test

# OSHA Electronic Reporting

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- > Submit electronically information on injuries and illnesses
  - > Already maintaining this information
- > Timetable
  - > Rule effective Jan. 1, 2017
  - > Compliance date by July 1, 2017
  - > 250+ employees required
  - > 20-249 employees in certain high risk industries
    - > Includes manufacturing

## Questions

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