Continuing Education - Texas
Understanding Life Sciences Property and Liability Exposures

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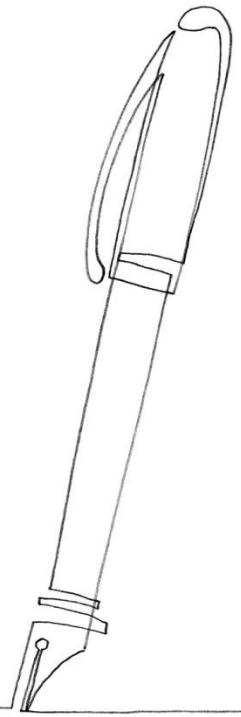
Life Sciences Product Leader



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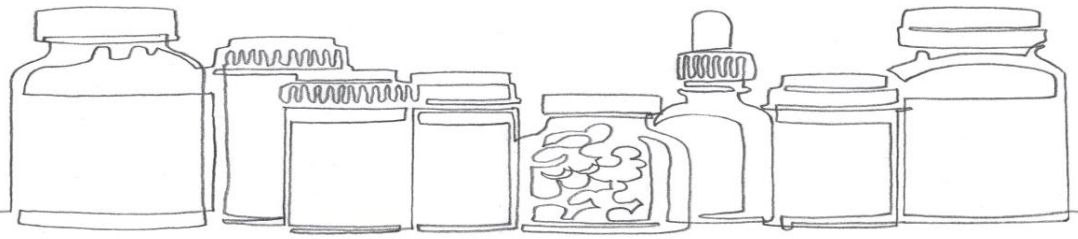
Discussion Points

- **Introduction**
- **Defining Life Sciences**
- **The Industry**
- **Underwriting Property Exposures**
- **Underwriting Clinical Trials Liability Exposures**
- **Underwriting Sold Products Liability for Medical Device and Pharmaceutical Exposures**



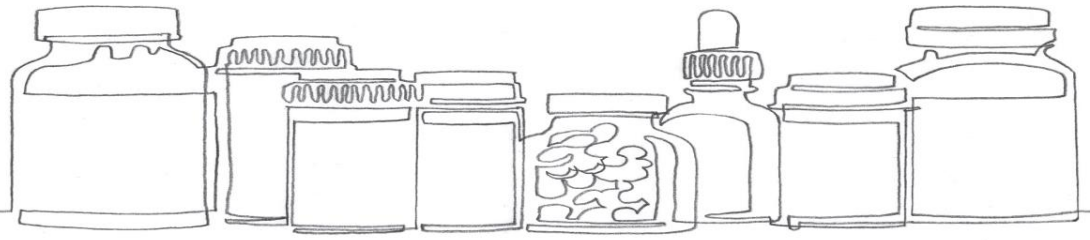
What is Life Sciences?

Universal with most insurance carriers:

- Pharmaceuticals/Biologics
- Biotechnology
- Laboratories (Diagnostic/Testing)
- Medical Devices (PMA, 510k)
- Service Providers
- Clinical Trials

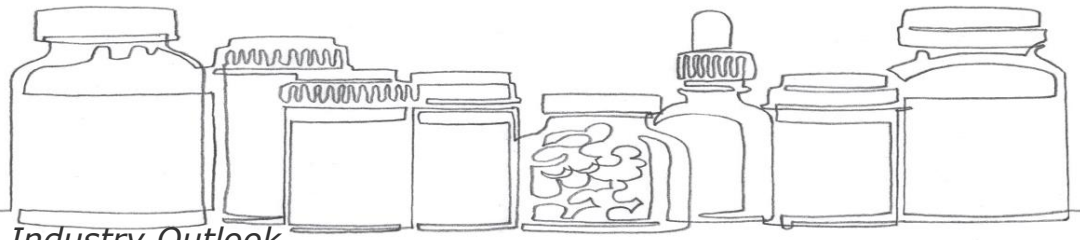
Depends on the Insurance Carrier:

- Telemedicine/Healthcare Information Technology
- Blood & Tissue Banks
- Dietary Supplements
- Cosmetics
- Research Institutes



The USA Life Sciences Industry

- **Global Industry*:**
  - USA leads the charge (7% growth in Biotech, 5% in Medical Device): Followed by: Japan, UK, France, Germany
  - **TOP 10 STATES** **(in terms of revenue generation, #of companies, employment):**
    1. California
    2. New York
    3. New Jersey
    4. Indiana
    5. Pennsylvania
    6. Illinois
    7. Massachusetts
    8. Minnesota
    9. North Carolina
    10. Florida



- **Deloitte, 2017 Life Sciences Industry Outlook*

Life Sciences Property

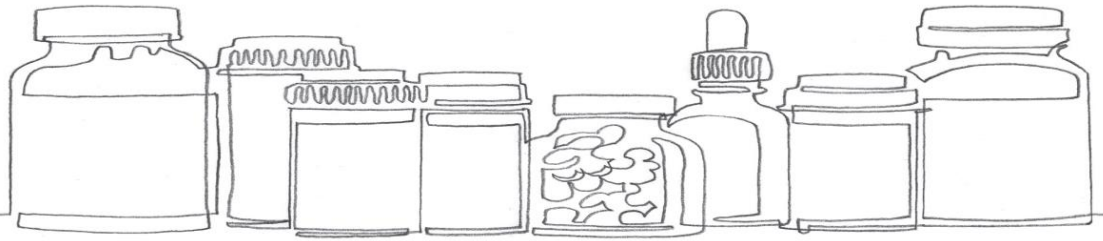
- **Real Property, Contents, Time Element**
- **Complex supply chains/Changing nature of the operations**
- **Research & Development property – Labs**
- **Vivariums**
- **Temperature sensitive property**
- **Boiler & Machinery**

Liability Exposures
What is a Human Clinical Trial?

- FDA definition of a clinical trial:

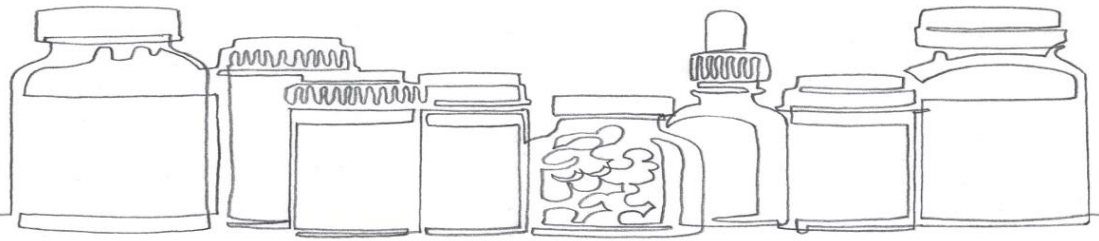
"Clinical trials are voluntary research studies, conducted in people, that are designed to answer specific questions about the safety and / or effectiveness of drugs, vaccines, other therapies, or new ways of using existing treatments"

www.fda.gov



Clinical Trials at a glance

- Documents: Protocol / Informed Consent
- Parties in the HCT process: Sponsors, CRO, Clinical Site, CRA, CI's, IRB's
- Phase I: Determines Safety (Pharmacokinetics and adverse events recorded), small number
- Phase II: Evaluate Safety and Efficacy, Larger scale, up to 2 yrs
- Phase III: Large scale, users have ailment, comparative
- Phase IV / Post Market Surveillance
- Claims issues



Clinical Trial Approvals

DEVICES:

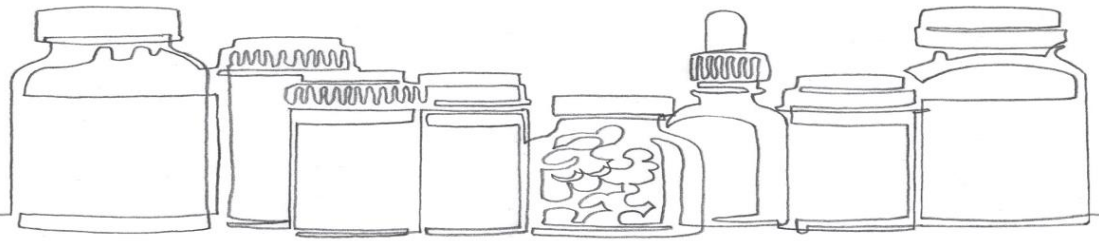
1. IDE – Investigational Device Exemption
2. PMA – Pre Market Approval for devices
3. 510k – Clearance for class II medical devices

BIOLOGICS:

1. BLA – Biologic License Application

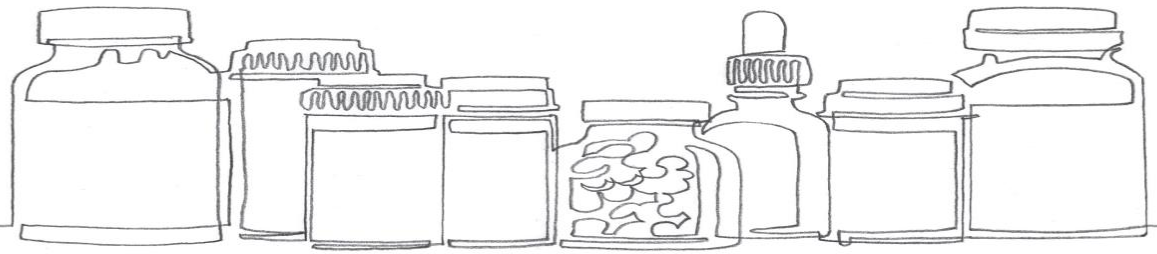
DRUGS:

1. IND – Investigational new drug application
2. NDA – New drug application



Underwriting for Sold Products – Pharmaceuticals and Medical Devices

- **Adverse Event history**
- **User profile and population**
- **Potential for misuse**
- **Off label usage / Off label promotion**
- **Current legal environment**
- **Claims**
- **Media / Social Media**
- **Mass Tort / Class Action Potential**
- **Regulatory compliance history**
- **Financials**
- **Risk management/Historical relationships with carriers**
- **Expanded Access / Compassionate Use**



QUESTIONS?

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