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Acquisitions/Licensing and Mergers What Are the Regulatory Requirements & Strategies to Consider?

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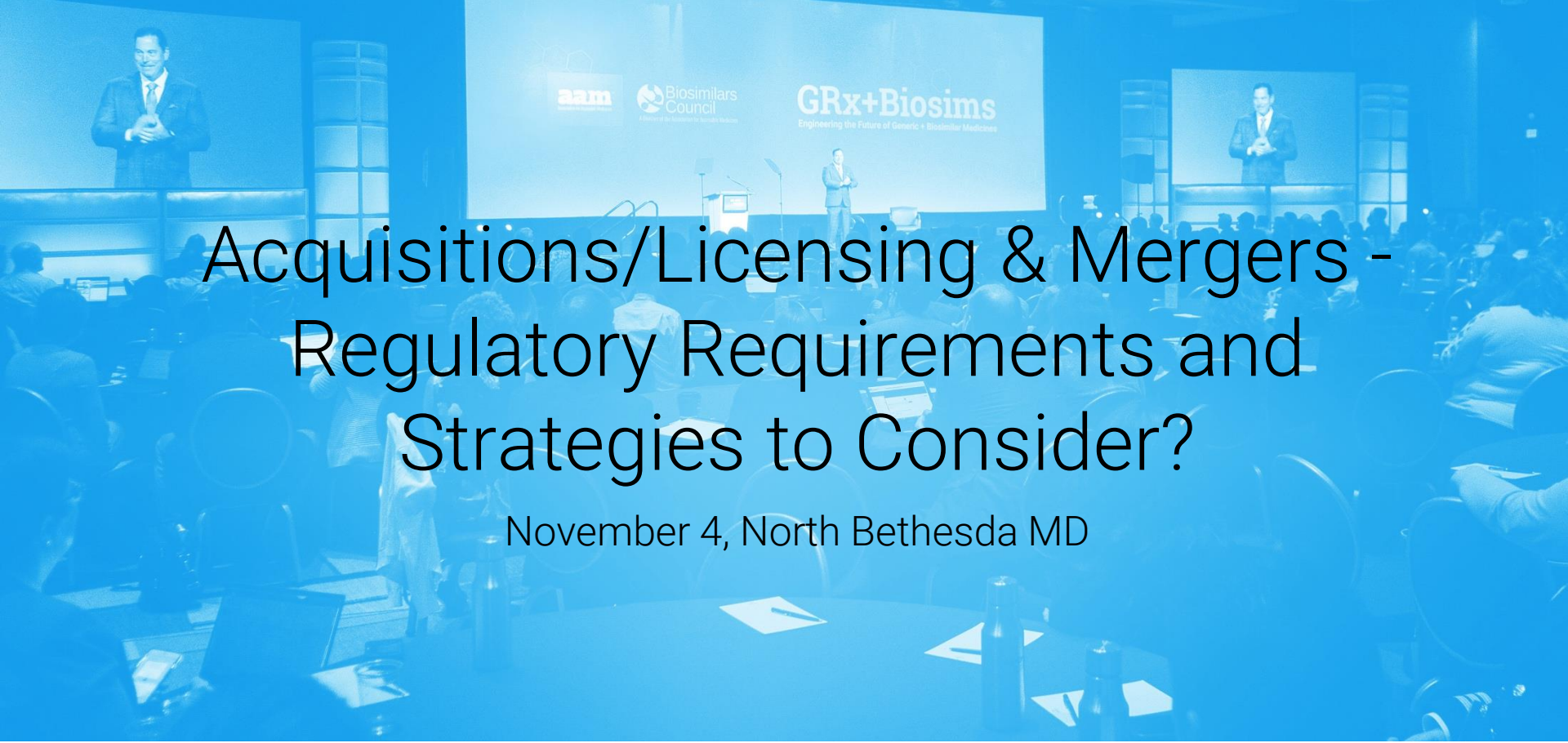

Acquisitions/Licensing & Mergers - Regulatory Requirements and Strategies to Consider?

November 4, North Bethesda MD

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Agenda

- Due Diligence
- Change in ownership of an application
- NDC / Labeling transition
- Site Transfers

Due Diligence

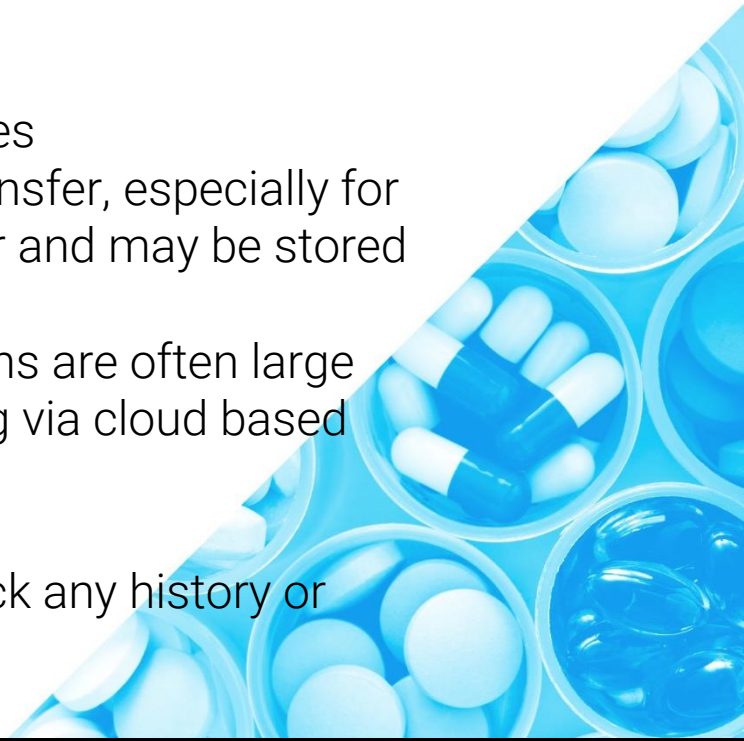
- Cannot underestimate the challenges that will be encountered when merging or acquiring a company or product(s)
  - Use of different
    - document management systems
    - submission publishing tools
    - Databases / spreadsheets
  - Pros/cons with respect to
    - keeping existing systems in place at legacy sites
    - Switching one or more acquired/merged sites to a common system
- Attention to detail
  - Compliance with regulations for ARs, Labeling updates, etc

Change in Ownership of an application

- New and former owners of application are required to submit notification of the transfer to FDA (see 21 CFR 314.72)
  - Former owner must state that all rights to the application have been transferred to the new owner
  - New owner
    - must commit to agreements, promises, and conditions made by the former owner and contained in the application
    - clarify the effective date of the change
    - Include a statement that they have a complete copy of the application, or request for a copy of the application from FDA's files

Change in ownership (cont)

- Coordination of transferring the application(s)
  - Need to ensure adequate time and resources
    - Gather and or scan applications for transfer, especially for older files that were submitted in paper and may be stored offsite
      - Files of scanned paper submissions are often large and present challenges for sharing via cloud based sites
      - Indexing / naming of files
  - Answering questions about old files that lack any history or knowledge transfer



NDC and Labeling Transition

- Clearly lay out responsibilities in technical service agreements (TSAs)
  - target completion dates before merger/acquisition is finalized
  - ensure all labeling source files and drug listings are transferred for applications part of the deal
- new owner must ensure labeling is updated with
  - new NDC number
  - new company trade dress
  - new contact information for reporting ADEs, located in the PI/medguide, if applicable
- Once labeling is updated , new NDCs/labeling needs to be drug listed

NDC and Labeling Transition (cont)

- If labeler codes are transferred to a new owner:
  - update ALL acquired Labeler Code Registrations with new company name and contact information
  - update should occur within 30 calendar days
    - FDA relies on this information to communicate with companies regarding their drug listings
    - Per 21 CFR 207.33(c)(2)
  - If a change in company name or DUNS number is made
    - all affected drug listings should be re-submitted to the agency when the change occurs [OR] in June or December, of that calendar year, per the regulations

Site Transfers

- It is critical that there is a good understanding of the differences between the originating site and receiving site
  - aid in the assessment and regulatory strategy
  - establish a clear understanding of the documents necessary to support the site transfer
    - e.g. split tablet testing
    - dissolution testing requirements, etc.
- Ensure that there is a realistic timeline for these activities and enough stock from the current site to prevent a drug shortage or supply interruption.
- Even if there are minimal changes proposed, there is no guarantee that everything will proceed without incident.


Thank you!
Questions?