Baculovirus Reference Material

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ISBioTech™
International Society for BioProcess Technology

Model Developed for the Ad5 Reference Material

- Overview
- Basic Tenants
- Cell Banks and Virus Seed Stock
- Working Group (WG)
- Regulatory Review
- Requests for Proposal, Bids, Acceptance, and Compliance
- Role of ISBioTech

Overview - Ad5 Reference Material

- Started in 2000 and Completed in 2002
- “Reference Material” and Not a “Standard”
- Intended for the Qualification / Validation of Internal Reference Materials and Assays
- Guiding Document / White Paper
- 13 Organizations Participated in the Characterization
- ALL Documents, Data and Documentation Reviewed by FDA Participant(s)
- All Actions Approved by Majority Vote of the WG (Essentially All Votes Were Unanimous)

Basic Tenants

- Well-Documented Material (not GMP)
- Actions Must Be Planned and Approved in Advance by WG (Prefer Unanimous Votes)
- Must be Able to Reproduce Material in the Future
- No Proprietary Raw Materials, Production Technology, or Analytical Techniques
- All Data and Donated Materials Become the Property of the WG for Intended Uses

Basic Tenants

- All Documentation, References, and Data Stored on Website
- Characterization Plan Reviewed and Data Analyzed by Approved Statistician
- Short-Term Stability, Sterility and Shipping Confirmation
- Ongoing Stability Studies
- Sample Retention Policy

Cell Banks and Virus Seed Stock

- Stored by Repository but Not For Sale – Property of Working Group for Intended Use
- Well-Characterized Master Cell Bank and Virus Seed Stock
- Working / Testing Cell Bank Tested for Identity, Sterility, Mycoplasma and In Vitro Adventitious Agents

Cell Banks and Virus Seed Stock

- Intended Uses Must Be Granted by Supplier Via MTA – No Licensing Fees
- Use of Cells Must be Approved by WG, and Only for Characterization, Stability Testing, and Production of Additional Reference Material Lots. After Use, Remaining Cells Must Be Destroyed

Working Group (WG)

- Open to All Serious Participants
- Should Represent Future Users with Right Mix of Industry and Academics, Plus Key Suppliers
- One Representative per Organization – Except for Regulatory Participants
- Includes Non-Voting Regulatory Participant(s)

Working Group

- Membership Documented by Written Invitation and Acceptance by Each Participant
- Member Contact Information Listed on Website
- Need to Establish an Executive WG for Long-Term Activities and Time-Sensitive Decisions – Should Include Regulatory Member

Regulatory Review

- All Plans, Documentation and Data Submitted for Review
- Regulatory Recommendations Must Be Adopted or Very Good Reasons Given
- Consensus Must Be Reached Before Proceeding
- As Needed, ISBioTech Will Mediate
- Participant from Office of Vaccines / CBER
- Would Like to Have European Regulatory Input

Requests for Proposal, Bids, Acceptance, and Compliance

- RFPs Will Be Sent Out for All Services and Materials Needed
- WG Will Draft and Must Approve RFPs
- All Bids Must Be Reviewed by WG and One Must Be Approved by WG for each RFP

Requests for Proposal, Bids, Acceptance, and Compliance

- Formal Acceptance Letters Will Be Sent for Each Awarded Bid
- WG Must Review All Documentation Submitted and Confirm That Work Was in Compliance with the Accepted Bid

Role of ISBioTech

- Coordinate WG Activities
- Facilitate WG Meetings
- Mediate Conflicts
- Act As Third Party for Regulatory Participation
- Host All Documentation, Data and Associated Materials on Website