

Baculovirus Reference Material

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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)



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Reference Material

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



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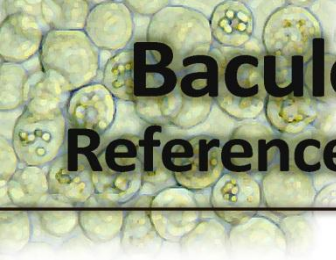
Reference Material

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



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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



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Reference Material

Working Group (WG)

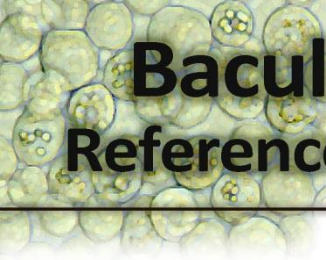
- Open to All Serious Participants
- Should Represent Future Users with Right Mix of Industry and Academics, Plus Key Suppliers
- One Representative per Organization – Except for Regulatory Participants
- Includes Non-Voting Regulatory Participant(s)

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

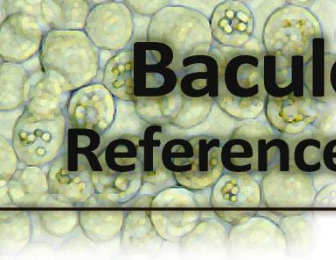


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Requests for Proposal, Bids, Acceptance, and Compliance

- 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

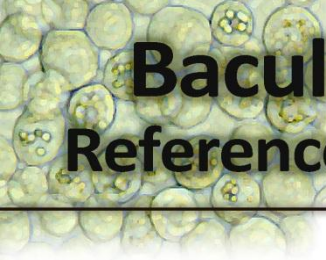


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Requests for Proposal, Bids, Acceptance, and Compliance

- 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



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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