

DIOSYNTH BIOTECHNOLOGY

PUBLICATIONS and PRESENTATIONS

PUBLICATIONS (PROCESS DEVELOPMENT)

1. **Removal of lipopolysaccharides from protein-lipopolysaccharide complexes by nonflammable solvents.** Lin, M.F., Williams, C., Murray, M.V., and Ropp, P.A. Journal of Chromatography B, Volume 816, Issues 1-2, Pages 167-174. February 25, 2005.
[View Abstract on Medline](#)
2. **Ion chromatographic quantification of cyanate in urea solutions: estimation of the efficiency of cyanate scavengers for use in recombinant protein manufacturing.** Lin, M.F., C. Williams, M.V. Murray, G. Conn and P.A. Ropp. (2004) J. Chromatography B, 803:353-362.
[View Abstract on Medline](#)
3. **Monitoring EDTA Process Residuals in Recombinant Protein Manufacturing Using High Performance Liquid Chromatography and a Terbium/Salicylate Complex.** Lin, M.F., M. Royal, K. Hayenga and G. Conn (2003). J. Chromatography B, 792:205-215.
[View Abstract on Medline](#)
4. **Identifying and Modulating Disulfide Formation in the Biopharmaceutical Production of a Recombinant Protein Vaccine Candidate.** Bouvier A, J. Chapline, R. Boerner, S. Jeyarajah, S. Cook, P.S. Acharya, I. Henderson, J.L. Schrimsher and S.R. Shepard. (2003) J Biotechnol. 103:257-71.
[View Abstract on Medline](#)
5. **Monitoring Manufacturing Process Yields, Purity and Stability of Structural Variants of PEGylated Staphylokinase Mutant SY161 by Quantitative Reverse-phase Chromatography.** Johnson, C, M. Royal, R. Moreadith, F. Bedu-Addo, S. Advant, M. Wan and G. Conn. (2003) Biomed Chromatogr. 17:335-44.
[View Abstract on Medline](#)
6. **Preformulation Development of PEGylated Staphylokinase SY161 using Statistical Design.** Bedu-Addo, F., R. Moreadith and S.J. Advant. (2002) AAPS PharmSci. 4:19.
[View Abstract on Medline](#)
7. **Recovery of Intracellular Recombinant Proteins from the Yeast *Pichia pastoris* by Cell Permeabilization.** Shepard, S.R., C. Stone, S. Cook, A. Bouvier, G. Boyd, G. Weatherly, D. Lydiard and J. Schrimsher. (2002) J. Biotechnol. 99:149-160.
[View Abstract on Medline](#)
8. **Initial Purification of Recombinant Botulinum Neurotoxin Fragments for Pharmaceutical Production using Hydrophobic Charge Induction**

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chromatography. Weatherly, G.T., A. Bouvier, D.L. Lydiard, J. Chapline, I. Henderson, J.L. Schrimsher and S.R. Shepard. (2002) J. Chrom. A, 952:99-110.

[View Abstract on Medline](#)

9. **An Enzyme-linked Immunosorbent Assay for Host Cell Protein Contaminants in Recombinant PEGylated Staphylokinase Mutant SY161.** Wan, M., Y. Wan, S. Rabideau, R. Moreadith, J. Schrimsher and G. Conn. (2002) J. Pharm. Biomed. Anal. 28:953-963.

[View Abstract on Medline](#)

10. **Routine Manufacture of Recombinant Proteins using Expanded Bed Adsorption Chromatography.** Shepard, S.R., G.A. Boyd and J.L. Schrimsher. (2001) Bioseparation, 10:51-56.

[View Abstract on Medline](#)

11. **Discoloration of Ceramic Hydroxyapatite used for Protein Chromatography.** Shepard, S.R., C. Brickman-Stone, J.L. Schrimsher and G. Koch. (2000) J Chromatogr A, 891:93-98.

[View Abstract on Medline](#)

12. **Large-scale Purification of Recombinant Human Angiostatin.** Shepard, S.R., R. Boucher, J. Johnston, R. Boerner, G. Koch, J.W. Madsen, D. Grella, B.K. Sim and J.L. Schrimsher. (2000) Protein Expr Purif. 20:216-27.

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PUBLICATIONS (GENERAL)

1. **Creation of a Well-Characterized Small Scale Model for High-Throughput Process Development.** Zhang, D. and Mostafa, S. BioProcess International Supplement Series. Vol. 7, Supplement 7, pp. 28-31. October 2009
2. **Tuning Oxygen Transfer in Small Scale Fermenters to Mimic Manufacturing Productivity: A Case Study.** Fairlee, J. and McNaull, S. 2009 BioProcess Yearbook.
3. **Optimization of a PEGylation Reaction Using Design of Experiments (DOE).** Holtschlag, S., Chavez, M., and Morar, S. Advertorial: BioProcess International Industry Yearbook 2008.
4. **Microbial Limit and Bioburden Tests, Validation Approaches and Global Requirements**, 2nd Edition. Clontz, L. Publisher: Taylor & Francis. September 2008.
5. **Como Evitar a Formação de Biofilmes em Sistemas de Água.** Clontz, L. Controle de Contaminação, São Paulo, Brasil. May 2008.
6. **Quality by Design in the CMO Environment.** Cook, S., Patton, K.A., and Bazemore, L.R. BioPharm International. Vol. 20, No. 12, p. 28. December 2007.
7. **Operational Excellence in Pharmaceutical Manufacturing.** Clontz, L. Chapter in College Level Instructional Book: "Industry Immersion Learning: The first generation real-life biotechnology and pharmaceutical cases for professional graduate students." This book was possible due to a grant received by NC State.
8. **Separation and Purification – What Really Needs to Change.** Koch, G. BioProcess International 5(6): pp S38-S42. October 2007.
9. **Operational Excellence in Pharmaceutical Manufacturing.** Chapter in College Level Instructional Book. Topic: Industry Case Studies, edited by Professor Lis Hamer, NCSU. July 2007.
10. **Application of Biophysical Characterization to the Development of Economically Viable Downstream Purification Processes of Proteins.** Acharya, P., Bazemore, R., and Cook, S. BioProcess International Yearbook 2007 Advertorial.
11. **Using Differential Scanning Calorimetry to Make Downstream Purification Processes Economically Viable: A Case Study.** Acharya, P., Bazemore, R., and Cook, S. Application Note. MicroCal. May 2007.
12. **A Comparison of Automated and Manual Cell Counts in Cell Culture.** Tholudur, A., Giron, L., Alam, K., Thomas, T., Garr, E., Weatherly, G., Kulowiec, K., Quick, M., and Shepard, S. Bioprocess International. October 2006.

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13. **Rapid Development of High Productivity Fed-Batch Cell Culture Processes Using a Platform Approach.** Garr, E., Tholudur, A., and Shepard, S. BioProcess International Industry Yearbook 2006. August 2006.
14. **Chemicals to Cell Culture. Biotech becomes a growing trend, aligned with traditional pharmaceutical culture.** PolICASTRO, E.F. Contributors: Baldauff, M. and Koch, G. InTech. June 1, 2006.
15. **PEGylation of Proteins: A Structural Approach.** Morar, A.S., Schrimsher, J.L., and Chavez, M.D. BioPharm International. April 2006, pp 34-49.
16. **Does Your CMO Offer You an "Insurance Policy"?** Acharya, P. Adams, G., and Boerner, R. BioProcess International. Industry Yearbook 2005.
17. **Defining Your Product Profile and Maintaining Control Over It: Part Three – Product-Related Impurities.** Boerner, R. and Clouse, K. BioProcess International. October 2005.
18. **Using Design of Experiments to Assess *E. coli* Robustness.** Tholudur, A., Sorensen, T., Zhu, X., and Shepard, S. BioProcess International. October 2005, pp. 46-48.
19. **Platform Technology for Developing Purification Processes.** M.H.M. Eppink. European Pharmaceutical Review. Autumn 2005, pp. 122-128.
20. **The Cubic Case Study: The Qualification/Validation of Equipment Under Changing Business Conditions.** Neal, C. Journal of Validation Technology. Volume 11, Number 2, Pages 144-152. February 2005.
21. **Partnering with Your CMO for a Successful Preapproval Inspection.** Gaido, M. and Persmark, M. BioProcess International. December 2004.
22. **Selecting the Most Appropriate Outsourcing Partner,** Kohm, J. (2003) BioProcess International, 11(Industry Yearbook):40-41
23. **Prerequisites for Successful Validation,** Neal, C., Jr. (2003) J. Validation Technology, 9:240-244
24. **Transdermal Process Validation,** Neal, C., Jr. (2003) Pharmaceutical Process Validation, Marcel Dekker, Inc., pp.237-287
25. **Aligning Expectations: Keys to Successful Contract Manufacturing,** Wheat, J. (2003) BioProcess Int., 1:34-40
26. **The Squeeze in Contract Biomanufacturing,** Lias, R., and S. Fogerty. (2002) GOR, 4:18-20
27. **The Squeeze in Contract Biomanufacturing,** Lias, R., and S. Fogerty. (2002) Pharm. Technol. Europe, 14:31-34

PRESENTATIONS (PROCESS DEVELOPMENT)

1. **Practical Applications of Metabolomics in Process Development.** Farnsworth, S. Metabolon Workshop. North Carolina Biotechnology Center. December 2, 2009.
2. **Increasing the Efficiency of Developmental Accelerated Stability Studies through the use of Differential Scanning Calorimetry (DSC) and Dynamic Light Scattering (DLS).** Bowers, K. IBC's 9th Annual Formulation Strategies for Protein Therapeutics. Raleigh, NC. October 15, 2009.
3. **Creation of a Well-Characterized Small Scale Model for High-Throughput Process Development.** Zhang, D. and Mostafa, S. BioProcess International Conference & Exhibition. Raleigh, NC. October 14, 2009.
4. **Best Practices and Risk Management as Applied to Technology Transfer.** Harter, C. and Parekh, D. BioProcess International Conference & Exhibition. Raleigh, NC. October 13, 2009.
5. **Process Development Characterization, Large Scale Production, and Quality Control of Follow-on Biologics.** Mostafa, S. BioProcess & Process Development Seminar. NCSU, BTEC. Raleigh, NC. September 24, 2009.
6. **Analytical Considerations during the Development of a Biosimilar mAb.** Adams, G. BIO 2009. Atlanta, GA. May 20, 2009.
7. **Complex Recombinant Proteins – when one size doesn't fit all.** Yi, Y., Bowers, K., Adams, G., and Acharya, P. BPI Analytical & Quality Summit. La Jolla, CA. May 4-6, 2009.
8. **Process Development, Characterization, Large Scale Production, and Quality Control of Follow-on Biologics.** Mostafa, S. Audio recording of presentation for IBC's On-Demand Online Educational Series, part of a 3 or 4 part series that will be uploaded at the BioProcess International website as a webinar. April 17, 2009.
9. **Process Development, Characterization, Large Scale Production, and Quality Control of Follow-on Biologics.** Mostafa, S. Antibody Development & Production. Carlsbad, CA. March 4-6, 2009.
10. **Applying Risk Management to Technology Transfer Programs.** Moore, C. and Baran, E. IBC's 4th Annual Technology Transfer for Biopharmaceuticals Conference. Carlsbad, CA. March 2-3, 2009.
11. **Microbial Identification Using Phenotypic Methods.** Clontz, L. Microrite Seminar. San Francisco, CA. February 19, 2009.
12. **Development and Scale-Up of Protein Purification Using the Baculovirus Expression System.** Parekh, D. The Williamsburg BioProcessing Foundation Conference. San Antonio, TX. February 2-4, 2009.

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13. **Microbial Limit and Bioburden Tests – A discussion on the latest hot topics.** Clontz, L. National Pharmaceutical Sciences Group. Toronto, Canada. January 19, 2009.
14. **A DOE Approach to Setting System Suitability Criteria for HPLC Assays.** Smith, C., Ragonese-Baldwin, H., and Adams, G. WCBP 2009 Conference. San Francisco, CA. January 12, 2009.
15. **Development of a Cell Culture Process for a Biosimilar.** Mostafa, S. IBC's 6th Annual Global Follow-on Biologics Conference. Bethesda, MD. November 17-18, 2008. **Managing Small Projects and Renovations in a cGMP Manufacturing Environment Course and Workshop.** Crosier, C. ASME BioProcessing Seminar. San Juan, Puerto Rico. November 12-13, 2008.
16. **Microbial Biofilms: A Costly Sticky Matter.** Clontz, L. Biofilm Networking Group Conference. RTP, NC. November 12, 2008.
17. **Analytical Considerations During the Development of a Biosimilar mAb (Poster presentation).** IBC's Well Characterized Biologicals Conference. Adams, G., Smith, C., Mostafa, S., and Murray, M. Reston, VA. November 10-12, 2008.
18. **Conventional and Capillary Differential Scanning Calorimetry: Valuable Tools for the Development of Therapeutic Protein Formulations and Manufacturing Processes.** Bowers, K.E. Advances in Biocalorimetry MicroCal Symposium. King of Prussia, PA. November 6, 2008.
19. **Project Management Framework and Tools – Don't Ever Underestimate the Basics.** Crosier, C. ISPE Annual Meeting. Boca Raton, FL. October 29, 2008.
20. **Stability Testing Program for Biotechnological/Biopharmaceutical Products: Developing a Stability Indicating Profile.** Patel, L. University of Wisconsin Madison, Pharmaceutical Engineering and Technology Series, Biopharmaceutical and Pharmaceutical Stability: Current Trends and Best Practices. Las Vegas, Nevada. October 27-28, 2008.
21. **Stability Requirements and ICH Guidelines for Biotechnology Products.** Patel, L. University of Wisconsin Madison, Pharmaceutical Engineering and Technology Series, Biopharmaceutical and Pharmaceutical Stability: Current Trends and Best Practices. Las Vegas, Nevada. October 27-28, 2008.
22. **Strategic Design of Analytical Development Programs to Meet the Life Cycle Needs of Biopharmaceutical Products.** Acharya, P., Adams, G., and Smith, C. IBC's Early to Late Stage Bioprocess Development Summit. Boston, MA. October 20, 2008.
23. **Microbial Identification Using Phenotypic Methods.** Clontz, L. Microrite, Inc. Raleigh, NC. October 16, 2008.

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24. **Development and Scale Up of Protein Production Using the Baculovirus Expression System.** Parekh, D. Baculovirus Technology Conference. Boston, MA. September 17-18, 2008.
25. **Cleaning Monitoring Strategies in a Biopharmaceutical Contract Manufacturing Facility.** Moore, C. IVT's Cleaning Validation and Critical Cleaning Processes Conference. Chicago, IL. July 14-17, 2008.
26. **Applying Structural and Stability Information in the Development of Protein Manufacturing Processes: A Biophysical Approach.** Bowers, K.E. IBC BioProcess International Analytical and Quality Summit. Cambridge, MA. June 4, 2008.
27. **Utilization of Mass Spectrometric Techniques for Monitoring Process Related Species During the Development of a Biopharmaceutical Process.** Adams, G. BioProcessing & Process Development Event, NC Biotechnology Center. RTP, NC. April 17, 2008.
28. **Method Qualification and Technology Transfer.** Clontz, L. 2008 PMF Conference on GMP in Microbiology. Dallas, TX. April 7-8, 2008.
29. **Quality Systems for the QC Microbiology Laboratory.** Clontz, L. 2008 PMF Conference on GMP in Microbiology. Dallas, TX. April 7-8, 2008.
30. **Development of a Monoclonal Antibody Purification Capture Step Using Design of Experiments to Determine Robust Conditions for Scale-up.** Vorontsova, L. and Bazemore, R. IBC's 20th International Antibody Development & Production Conference. San Diego, CA. March 12-14, 2008.
31. **Challenges in the Identification of Critical Parameters for Biotechnology Processes.** Advant, S. and Koch, G. FIP Quality International Meeting. London, England. November 26, 2007.
32. **Feed Strategies and Equipment Requirements for Increased Productivity in High Density Fermentation Cultures.** McNaul, S. North Carolina Biotechnology Center BioProcessing & Process Development Seminar Series. RTP, NC. November 15, 2007.
33. **Disinfectant Efficacy for Equipment Cleaning – A Case Study.** Clontz, L. Biofilm Networking Group (BNG) Conference. RTP, NC. November 14, 2007.
34. **Managing Government-Funded Pharmaceutical R&D and Manufacturing Contracts.** Adkins, B. RTP PMI. Quintiles, Durham, NC. November 14, 2007.
35. **Product Related Impurity Removal and Scale up of a Monoclonal Antibody Process Using Hydrophobic Charge Interaction (HCIC) Chromatography.** Ediriwickrema, C., Fayer, V., Cook, S., Lin, M.F., Patton, K., Bazemore, R., and Ropp, P. Pall Seminar Series 2007 Comprehensive Chromatography. RTP, NC. November 14, 2007.
36. **Development of a Monoclonal Antibody Purification Capture Step Using Design of Experiment for an Industrial Application.** Vorontsova, L. and Bazemore, R. SERMACS 2007. Greenville, SC. October 24-27, 2007.

37. **Stability Indicating Profile for Biotechnology Products: Considerations for development of stability testing program for biopharmaceuticals.** Patel, L. University of Wisconsin Madison. Pharmaceutical Engineering and Technology Series. Biopharmaceutical and Pharmaceutical Stability: Current Trends and Best Practices. Las Vegas, NV. October 22-23, 2007.
38. **Stability Requirements and ICH Guidelines for Biotechnology Products.** Patel, L. University of Wisconsin Madison. Pharmaceutical Engineering and Technology Series. Biopharmaceutical and Pharmaceutical Stability: Current Trends and Best Practices. Las Vegas, NV. October 22-23, 2007.
39. **A Methodology for Testing the Removal of a Polydimethylsiloxane Based Antifoam from Biopharmaceutical Products.** (Poster) Workman, C. ISPPP, Orlando, FL. October 21-23, 2007.
40. **Pre-formulation and Biophysical Screening as Tools to Support Process Development.** Bowers, K., Davis-Searles, P. (Poster Presenter), Morar-Mitrica, S., Cook, S., Bazemore, R., and Acharya, P. IBC's 7th Annual Formulation Strategies for Protein Therapeutics Conference. Boston, MA. October 1-3, 2007.
41. **Applying Quality by Design Concepts to Biotechnology Products.** Koch, G. and Bazemore, R. BioProcess International Conference. Boston, MA. October 1-4, 2007.
42. **Utilization of Mass Spectrometric Techniques for Monitoring Process Related Species during the Development of a Biopharmaceutical Process.** Adams, G. CASSS Mass Spectrometry Conference. Montreal, Canada. September 5-7, 2007.
43. **Structural Studies as a Screening Tool in Development of Protein Purification Processes.** Acharya, P. 2007 Current Trends in Microcalorimetry. Boston, MA. July 18-21, 2007
44. **EDTA Binding to Anion Exchange Resin.** Holtschlag, S.R. and Runyon, G.T. 2007 AAPS National Biotechnology Conference. San Diego, CA. June 24-27, 2007.
45. **Characterization of Product Related Species during the Development of a Biopharmaceutical Process for Antibody Molecule X.** (Poster presented by Katherine Bowers) Aldridge, J.E., Wilson, M.L., Morar-Mitrica, A.S., Holtschlag, S.R., Chavez, M.D., and Boerner, R.J. AAPS National Biotechnology Conference. San Diego, CA. June 2007.
46. **Preformulation and Biophysical Screening as Tools to Support Process and Formulation Development.** Bowers, K., Acharya, P., Bazemore, R., and Cook, S. BioProcessing & Process Development Event. NC Biotechnology Center. RTP, NC. May 17, 2007.
47. **Process Risk Assessment Applied to Microbial Control in Biotech Manufacturing.** Clontz, L. PDA Southeast Chapter Spring 2007 Meeting. RTP, NC. May 2, 2007.

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48. **Structural Studies as a Screening Tool for Optimization of Protein Purification Processes.** Acharya, P., Morar, S., Bowers, K., Bazemore, R., and Boerner, R. IIR Conference: Formulation and Forced Degradation Strategies for Biomolecules. San Diego, CA. March 19-21, 2007.
49. **Transfer and Management of a Bio-Manufacturing Project Across Continents.** Advant, S. IBC Meeting on Outsourcing. Carlsbad, CA. February 26 – March 2, 2007.
50. **Rapid Gram Quantity Production of Monoclonal Antibodies from Hybridomas for Preclinical Studies.** Pelletier, G.W., Acharya, P.S., Holtschlag, S.R., Denning, L.R., and Murray, M.V. (Poster) Antibody Development & Production Conference. Carlsbad, CA. February 26 – March 2, 2007.
51. **Rapid Development of a High-Productivity Fed-Batch Cell Culture Process Using a Platform Approach.** Garr, E.R., Tholudur, A., Giron, L., Newman, E., Yanagawa, R., and Shepard, S. IBC: 18th Antibody Development and Production Conference. Carlsbad, CA. February 27, 2007.
52. **Method Transfers During Different Stages of Development.** Rooney, M.M. IBC Technology Transfer for Biopharmaceuticals. Carlsbad, CA. February 26-27, 2007.
53. **Development of Antibody Producing Chinese Hamster Ovary Cell Lines by Traditional and Non-Traditional Methods.** (Poster and Presentation) Henry, A., Thornton, R., Ediriwickrema, C., Quick, M., and Murray, M. Keystone Symposia, Lake Louise Alberta, Canada. February 1-6, 2007.
54. **Viral Control Strategies for Cell Based Manufacturing Processes.** Zemler, M. and Kitchen, C. (C. Kitchen presenter) BioPharma Operations Excellence Consortium. Andover, MA. December 7, 2006.
55. **Critical Attributes of Process Materials.** Koch, G. IBC's 3rd Disposables for Biopharmaceutical Production Conference. Orlando, FL. December 6, 2006.
56. **Viral Control Strategies for Cell Based Manufacturing Processes.** Zemler, M. and Kitchen, C. (M. Zemler presenter) BioPharma Operations Excellence West Coast Consortium. Oceanside, CA. October 19, 2006.
57. **Nonaffinity Purification of an Antibody Molecule X Produced in *Pichia pastoris*.** Vorontsova, L.A., Pelletier, G.W., Kingsley, G.A., Jeyarajah, S., Schrimsher, J.L., and Chavez, M.D. Pichia Protein Expression Conference 2006. San Diego, CA. October 8-11, 2006.
58. ***Pichia Pastoris* Fermentation Process Development.** Zhu, X., Baker, B., Mandulak, P., Sorensen, E.T., and Shepard, S. Pichia Protein Expression Conference 2006. October 8-11, 2006.
59. **Stability Indicating Profile for Biotechnology Products: Considerations for development of stability testing program for biopharmaceuticals.** Patel, L. IVT: Stability Testing Conference. Dublin, Ireland. September 26-28, 2006.

60. **Stability Requirements and ICH Guidelines for Biotechnology Products.** Patel, L. IVT: Stability Testing Conference. Dublin, Ireland. September 26-28, 2006.
61. **Characterization of Process/Product Related Species During the Development of a Biopharmaceutical Process for hIL13-PE38QQR.** Adams, G. and Rooney, M. Mass Spec 2006: Third Symposium on the Practical Applications of Mass Spectrometry in the Biotechnology and Pharmaceutical Industries. La Jolla, CA. September 6-8, 2006.
62. **Differential Scanning Calorimetry in the preformulation/formulation development of biopharmaceuticals.** Acharya, P. and Boerner, R. 34th Annual Conference of the North American Thermal Analysis Society: Short course on Thermal analysis of Pharmaceuticals. Bowling Green, KY. August 5-6, 2006.
63. **Development and Optimization of purification processes using biophysical techniques.** Acharya, P., Cook, S., and Boerner, R. 34th Annual Conference of the North American Thermal Analysis Society: Short course on Thermal analysis of Pharmaceuticals. Bowling Green, KY. August 5-6, 2006.
64. **Microbiological Control in Pharmaceutical and Biotech Manufacturing.** Clontz, L. IVT: Microbiology Event of the Year for Pharmaceutical, Biotechnology & Medical Device Operations. Washington, DC. June 22, 2006.
65. **Rapid Development of Fed-batch Conditions for Therapeutic Protein Production Using CHO Cells.** Tholudur, A., Garr, E., Giron, L. Yanagawa, R., Newman, E., and Shepard, S. BioLOGIC Europe 2006 Mini-Conference. Diosynth Biotechnology, Oss, The Netherlands. June 22, 2006.
66. **CMC Activities to Support Fast-Track Approval of a Complex, Cytotoxic Tumor Targeting Fusion Protein.** Shepard, S., Quick, M., Tholudur, A., Weatherly, G., and Zhu, X. BioLOGIC Europe 2006 Mini-Conference. Diosynth Biotechnology, Oss, The Netherlands. June 22, 2006.
67. **Stability Requirements and ICH Guidelines for Biotechnology Products.** Patel, L. IVT: Stability Testing Conference. San Diego, CA. June 20, 2006.
68. **Stability Indicating Profile for Biotechnology Products: Considerations for Development of Stability Testing Program for Biopharmaceuticals.** Patel, L. IVT: Stability Testing Conference. San Diego, CA. June 20-23, 2006.
69. **Pre-formulation Strategies & Protein Characterization Tools.** Advant, S. AAPS National Biotechnology Conference. Boston, MA. June 21, 2006.
70. **Analytical Instrument Qualification.** Snyder, J.M. Institute of Validation Technology. San Juan, Puerto Rico. June 21, 2006.
71. **Setting Specifications During the Development Cycle of Biologics – Analytical Considerations.** Advant, S. BIO-Japan. Tokyo, Japan. May 17-19, 2006.

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72. **Process Validation, What are the Real Needs? A Case Study.** Johnson, A.M. IVT: European Validation Week. Amsterdam, The Netherlands. May 2-5, 2006.
73. **Equipment Validation, Determining the True Requirements for the Entire Program.** Johnson, A.M. IVT: European Validation Week. Amsterdam, The Netherlands. May 2-5, 2006.
74. **PEGylation Cycling: A Technique for Maximizing Protein PEGylation Reaction Yields.** Chavez, M.D., Pelletier, G.W., Oliver, E.K., Traviglia, S.L., and Schrimsher, J. Recovery of Biological Products XII. Litchfield, AZ. April 2-7, 2006.
75. **Defendable, Dependable GMP Documentation.** Easterly, M.C. Institute of Validation Technology Conference. Amsterdam, The Netherlands. March 31, 2006.
76. **Developing an Effective Internal Audit Program.** Easterly, M.C. Institute of Validation Technology Conference. Amsterdam, The Netherlands. March 30, 2006.
77. **Use of Statistical Design to Evaluate the Stability of Proteins during Pre-formulation.** Advant, S. Formulation & Forced Degradation Strategies for Biopharmaceuticals Conference. San Francisco, CA. March 27-29, 2006.
78. **Approaches to Pre-formulation / Formulation Development for a Biopharmaceutical Product.** Acharya, P. Formulation & Forced Degradation Strategies for Biopharmaceuticals Conference. San Francisco, CA. March 27-29, 2006.
79. **Formulation Development – The Analytical Perspective.** Advant, S. Formulation & Forced Degradation Strategies for Biopharmaceuticals Conference. San Francisco, CA. March 27-29, 2006
80. **Pre-formulation Development to Support Purification and Formulation Development.** Acharya, P. Formulation & Forced Degradation Strategies for Biopharmaceuticals Conference. San Francisco, CA. March 27-29, 2006.
81. **Process Risk Assessment to Ensure Microbial Contamination Control.** Clontz, L. North Carolina Biotech Center Conference. RTP, NC. March 16, 2006.
82. **Lessons Learned from Transferring a Validated Process.** Gilleskie, G. and McCuen, B. IBC's 10th International Conference Process Validation for Biologicals. Carlsbad, CA. February 28, 2006.
83. **Preformulation Development to Support Process and Formulation Development – An Insurance Policy.** Acharya, P., Morar, S., Bowers, K., Cook, S. and Bazemore, R. BioProcess International European Conference & Exhibition. Prague, Czech Republic. February 21-23, 2006.

84. **Protection Against Protein Carbamylation using Non-Ethylene Diamine-Like Compounds.** Morar, S., Ropp, P., Schrimsher, J., Wan, M., and Chavez, M. Joint Structural Genomics and Frontiers in Structural Biology Symposia. Keystone, CO. January 29 – February 3, 2006.
85. **Identification and Prevention of Potential Method Transfer Problems.** Dhar, J. International Institute of Research: Technology Transfer Conference. Orlando, FL. December 5-7, 2005.
86. **Establishing Guidelines for Tech Transfer When Using CMOs.** Wheat, J. Contract Manufacturing: Utilizing Outsourcing as a Competitive Advantage. San Diego, CA. November 29 – December 1, 2005.
87. **Establishing a Stability Testing Program in a Biotechnology Environment.** Patel, L. IVT: Stability Testing Conference. Amsterdam, The Netherlands. November 29 – December 2, 2005.
88. **Stability Considerations for Biotechnology Products: Issues related to the development of stability programs for bio-pharmaceuticals as they advance from pre-clinical development to commercialization.** Patel, L. IVT: Stability Testing Conference. Amsterdam, The Netherlands. November 29 – December 2, 2005.
89. **Establishing Guidelines for Tech Transfer When Using CMOs.** Koch, G. Contract Manufacturing: Utilizing Outsourcing as a Competitive Advantage. San Diego, CA. November 29 – December 1, 2005.
90. **Achieving Purity of PEGylated Proteins by Analyzing Impurities.** Orpiszewski, J. Institute for International Research: Impurities for Biomolecules Conference. San Francisco, CA. November 14-16, 2005.
91. **Streamlining Technology Transfer for Internal & Outsourced Projects.** Advant, S.J. BioProcess International Asia-Pacific Conference & Exhibition. Singapore. November 8, 2005.
92. **GMP Requirements for Commercial Fermentation Manufacturing.** McNaull, S. Recent Advances in Fermentation Technology (RAFT) VI Conference. Long Beach, CA. November 6-9, 2005.
93. **Novel application for purification of Monoclonal antibodies.** Eppink, M.H.M. Amsterdam. October 25-26, 2005.
94. **Industry Perspectives on Current FDA Guidelines on Stability Testing for Biotech Products.** Brown, T.M. IIR Stability Testing Conference. London, UK. October 25, 2005.
95. **Stability Considerations for Biotechnology Products.** Patel, L. University of Wisconsin Madison – Pharmaceutical Engineering and Technology Series. Pharmaceutical Stability: Current Trends and Best Practices. Las Vegas, NV. October 24, 2005.
96. **Establishment of a Stability Testing Program in a Biotechnology Environment.** Patel, L. University of Wisconsin Madison – Pharmaceutical

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Engineering and Technology Series. Pharmaceutical Stability: Current Trends and Best Practices. Las Vegas, NV. October 24, 2005.

97. **Managing Compendia Changes Internally and Externally in a Biotech Environment.** Patel, L. North Carolina Biotechnology Center: Bioprocessing Process Development. RTP, NC. October 20, 2005.
98. **High Throughput Screening (HTS).** Eppink, M.H.M. NBV Meeting. Amersfoort. October 5, 2005.
99. **Contamination Control in Pharmaceutical and Biotech Manufacturing.** Clontz, L. Seminar Sponsored by SREQ. São Paulo and Rio de Janeiro, Brazil. October 3-6, 2005.
100. **A Risk Based Approach to Effective Backup and Recovery.** Snyder, J. IVT: Laboratory Regulations, Controls, and Compliance Event. San Francisco, CA. September 27-30, 2005.
101. **Effective Laboratory System Data Backup and Retention.** Snyder, J. IVT: Laboratory Regulations, Controls, and Compliance Event. San Francisco, CA. September 27-30, 2005.
102. **A Case Study for the Use of Laboratory Scale Techniques to Pack and Evaluate Production Scale Columns.** Runyon, G. BioProcess International World Conference and Exhibition. Boston, MA. September 19-22, 2005.
103. **Comparison of the dhfr and MAR (Matrix Attachment Region) Approach to Cell Line Development.** Henry, A.T., Ediriwickrema, C.P., Thornton, R.R., and Murray, M.V. IBC: 2nd BioProcess International Conference and Exhibition. Boston, MA. September 19-22, 2005.
104. **Mass Spectrometric Approaches to Product Characterization During the Development of a Biopharmaceutical Process.** Adams, G., Smith, C., Weatherly, G., and Quick, M. Second Symposium on the Practical Applications of Mass Spectrometry in the Biotechnology and Pharmaceutical Industries. Boston, MA. September 12-13, 2005.
105. **Protein PEGylation: an attempt to control the extent of reaction.** Morar, S., Ediriwickrema, C., Schrimsher, J., and Chavez, M. 9th International Congress on Proteins and Amino Acids. Vienna, Austria. August 8-12, 2005.
106. **Troubleshooting Test methods for Raw Materials.** Patel, L. The Williamsburg BioProcessing Foundation: Raw Materials & Contract Services for Mammalian Cell Products. Kansas City, MO. July 18-20, 2005.
107. **Equipment Qualification Case Study.** Crader, D. Validation and cGMP Compliance Workshop Series. San Juan, Puerto Rico. July 12-14, 2005.
108. **Platform Technology.** Eppink, M.H.M., Schreurs, and R., Gijzen, A. 13th International BPP Conference. Delft. June 20-24, 2005.

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109. **Changeover Practices in a Multi-Product Biotech Manufacturing Facility.** Johnson, A. IVT: Active Pharmaceutical Ingredients Event. Dublin, Ireland. June 21-24, 2005.
110. **Quality Assurance and Quality Control in the Biopharmaceutical Industry.** Easterly, M.C. NC Biotechnology Center: Summer 2005 Faculty Enhancement Workshop. RTP, NC. June 16, 2005.
111. **Analysis and Characterization of PEGylated Proteins.** Orpiszewski, J. AAPS: Short Course on Development of PEGylated Biopharmaceuticals. San Francisco, CA. June 9, 2005.
112. **Comparison of the dhfr and MAR (Matrix Attachment Region) Approach to Cell Line Development.** Ediriwickrema, C.P., Henry, A.T., Thornton, R.R., Murray, M.V., Girod, P.A., Calabrese, D., and Mermod, N. 19th Meeting of the European Society for Animal Cell Technology. Harrogate, UK. June 5-9, 2005.
113. **Preformulation/Biophysical Characterization to Support Protein Purification and Formulation Development of Proteins.** Acharya, P. (Speaker and Moderator of Roundtable) AAPS National Biotechnology Conference. San Francisco, CA. June 5-8, 2005.
114. **Optimization and Scaling up of a Cleaning Protocol Following the Application of *Escherichia coli* Homogenate on Streamline SP.** Morar, S., Ropp, P., Schrimsher, J., and Williams, C. CAP 05: Initial Recovery and Capture Technologies. Phoenix, AZ. May 22-25, 2005.
115. **Comparison of a Traditional and Non-Traditional Approach to Cell Line Development.** Henry, A.T., Ediriwickrema, C.P., Thornton, R.R., Schrimsher, J. and Murray, M.V. (presenter). Cambridge Healthtech Institute: 6th Recombinant Antibodies Conference. Cambridge, MA. May 18-19, 2005.
116. **Implementing a Successful Process Validation Program.** Parekh, D. Barnett International Conference: Contract Manufacturing. Philadelphia, PA. May 13, 2005.
117. **Stability Considerations for Biotechnology Products: Issues related to the development of stability programs for bio-pharmaceuticals as they advance from pre-clinical development to commercialization.** Patel, L. Institute of Validation Technology: Stability Testing. Philadelphia, PA. May 12, 2005.
118. **Establishment of a Stability Testing Program in the Biotechnology Environment.** Patel, L. Institute of Validation Technology: Stability Testing. Philadelphia, PA. May 11, 2005.
119. **Design of Experiments (DOE) Applications in Process Development.** Tholudur, A., Zhu, X., Alam, K., Chang, N., Baker, B., Sloop, J., Smith, C., and Shepard, S. NC Biotech Center: Bioprocessing and Process Development Seminar. RTP, NC. April 21, 2005.
120. **Platform Technology.** Eppink, M.H.M., Schreurs, R., and Gijzen, A. 2nd IPEP Meeting. Basel. April 20, 2005.

121. **Platform Technology for Developing Purification Processes.** Eppink, M.H.M., Schreurs, R., and Gijzen, A. ACS Meeting. San Diego, CA. March 13-17, 2005.
122. **How do CMOs evaluate potential clients, and how do clients evaluate CMOs – Panel Discussion.** Persmark, M. IBC: Biopharmaceutical Outsourcing, Contracting and Partnering. San Diego, CA. March 7-8, 2005.
123. **Establishment of a Stability Testing Program in the Biotechnology Environment.** Patel, L. SWE, Inc.: Advances and Efficiencies in Stability Testing for the Pharmaceutical & BioTech Industry. San Diego, CA. March 7-8, 2005.
124. **Extremely Fast Development and Manufacturing of Phase III Clinical Supplies of a Recombinant Fusion Protein: A Case Study of a Joint Originator – CMO Effort.** Shepard, S., Weatherly, G., Smith, C., Sorensen, T., and Zhu, X. IBC: Biopharmaceutical Outsourcing, Contracting and Partnering: Discovering and Enhancing Strategic Options in Biomanufacturing. San Diego, CA. March 7-8, 2005.
125. **Enhancement of Transgene Expression in Mammalian Cells by Matrix Attachment Regions.** Henry, A.T., Ediriwickrema, C.P., Thornton, R.R., Schrimsher, J.L., and Murray, M.V. Poster Presentation. Keystone Symposium B5. Santa Fe, NM. February 17-22, 2005.
126. **A Complementary Mass Spectrometry Approach to the Identification of Host Cell Protein Impurities in Therapeutic Biopharmaceutical Processes.** Adams, G., Smith, C., Orpizewski, J., and Boerner, R. Williamsburg BioProcessing Foundation: Characterization & Comparability for Complex Biological Products. Coronado, CA. January 24-26, 2005.
127. **To Document or Not to Document: Providing Effective Supporting Documentation for Changes.** Easterly, M.C. Institute of Validation Technology: Change Control Conference. Elizabeth, NJ. January 24-27, 2005.
128. **Make Plain, Explain, Train: Training Personnel on Change Control Procedures.** Easterly, M.C. Institute of Validation Technology: Change Control Conference. Elizabeth, NJ. January 24-27, 2005.
129. **Introduction to Contract Manufacturing.** Persmark, M. Elon College: Entrepreneurship in Biotechnology. January 13, 2005.
130. **Applications of Differential Scanning Calorimetry during Pre-Formulation and Formulation Development of Recombinant Proteins.** Acharya, P. Differential Scanning Calorimetry: An Essential Tool for Protein Stability and Pharmaceutical Formulation Studies. Cambridge, MA. December 10, 2004.
131. **A Case Study of the Use of Small-Scale and Large-Scale Techniques to Identify, Improve, and implement Changes to Column Packing Efficiency Test Methods and Column Packing Procedures at purification Scale.** Runyon, G. and A. Allen. NC Biotechnology Center, RTP, NC, 20 May,

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2004.

132. **Preformulation and Biophysical Characterization to Support Purification and Formulation Development.** Acharya, P. AAPS National Biotechnology Conference. Boston, MA, 16-19 May, 2004.
133. **Stability Considerations for Biotechnology Products.** Brown, T. AAPS National Biotechnology Conference. Boston, MA, 16-19 May, 2004.
134. **Large scale production of pharmaceutical proteins in a multi-product, multi-process environment.** Meijden, P.v.d. The Williamsburg BioProcessing Conference Europe. Amsterdam, The Netherlands, March 15-19, 2004.
135. **Biophysical Characterization in the Preformulation and Formulation Development of Biopharmaceuticals.** Acharya, P. IBC: Formulation & Drug Delivery Strategies for Biopharmaceuticals. Munich, Germany, Feb. 17-18, 2004.
136. **In-Process Monitoring of Selected Recombinant Proteins and Monoclonal Antibodies.** Jeyarajah, S. WilBio: Characterization and Comparability for Complex Biological Products. Coronado, CA, January 26-28, 2004.
137. **Depth Filtration: A Brief Case Study of Scale-Up to 2,000 L.** Bazemore, R.L. IBC: Cell Culture and Upstream Processing. San Diego, CA, Dec. 8-10, 2003.
138. **Increased Dynamic Binding Capacity in Ion Exchange Chromatography by Addition of Polyethylene Glycol.** Chavez, M., M. Wan and J. Schrimsher. Recovery of Biological Products XI. Banff, Alberta, Canada, Sep. 14-19, 2003.
139. **The Conjugation of PEG and Protein: Parameter Design using a Scale-down Model for Protein PEGylation Reactions.** Morar, S.A., C.P. Ediriwickrema, J.L. Schrimsher and M.D. Chavez. IBC: Scaling-Up from Bench to Clinic and Beyond. Research Triangle Park, NC, August 4-6, 2003.
140. **Evaluation of Analytical Methods for Quantification of Antibodies.** Royal, M., S. Jeyarajah, S. Traviglia, D. Brown, V. Fayer, G. Conn and R. Boerner. WCBP 2003, 7th Symposium on the interface of Regulatory and Analytical Sciences for Biotechnology Health Products. San Francisco, CA, Jan. 7-10, 2003.
141. **Assessing Instability of Proteins Expressed in *Pichia pastoris*.** Jeyarajah, S., J. Chapline, R. DePaz, C. Johnson, R. Sullivan, M. Wan, G. Weatherly, S. Shepard, G. Conn, I. Henderson, R. Boerner and S. Advant. WCBP 2003, 7th Symposium on the interface of Regulatory and Analytical Sciences for Biotechnology Health Products. San Francisco, CA, Jan. 7-10, 2003.
142. **The Application of Hydrophobic Charge Induction Chromatography to the Capture of Intracellular Proteins Produced in the Yeast *Pichia pastoris*.** Weatherly, G.T., A. Bouvier, I. Henderson, J. Schrimsher and S.R. Shepard. IBC Recovery and Purification, San Diego, CA, Nov. 18-19, 2002.

143. **Biophysical Characterization and Preformulation Development of a Heavy Chain Fragment of Botulinum Serotype A for Vaccine Development.** Acharya, P.S., C. Johnson, S. Jeyarajah, J. Ahn, R. Boerner, S.R. Shepard, I. Henderson, S. Advant and F.K. Bedu-Addo. AAPS Meeting, Toronto, Canada, October 21-25, 2002.
144. **Application of Expanded Bed Chromatography in Biopharmaceutical Manufacturing.** Shepard, S.R. ACS National Meeting, Boston, MA, August 18-22, 2002.
145. **The Application of Hydrophobic Charge Induction Chromatography to the Capture of Intracellular Recombinant Proteins produced in the Yeast *Pichia pastoris*.** Shepard, S.R., G.T. Weatherly, A. Bouvier, I. Henderson and J. Schrimsher. Prep 2002, Washington, D.C., June 16-19, 2002.
146. **Novel Approach to Qualification of a Humanized Monoclonal Antibody Binding Assay Using the Biacore 3000.** Patel, L., C. Crumpler, C. Autry, S. Robinson, J. Johnston, T. Brown and R. Boerner. IBC: 4th Annual International Intensive Symposium: Biological Assay Development and Validation, May 2002.
147. **Designing a Successful Lyophilization Process – What is right for your product?** Bedu-Addo, F.K. 2nd Barnett International Conference on Lyophilization for the Pharmaceutical and Biotechnology Industries, Philadelphia, May 16-17, 2002.
148. **Use of Statistical Design in Evaluating the Stability of a PEGylated Protein During Pre-Formulation.** Bedu-Addo, F.K. IBC 2nd International Conference: Formulation Strategies for Biopharmaceuticals. Overcoming Macromolecular Instability and Dosage Form Challenges for Successful Commercialization, Miami, FL, February 4-6, 2002.
149. **Characterization of Recombinant Heavy Chain Fragments of Botulinum Neurotoxin, Serotype A and B.** Boerner, R., J. Chapline, J. Ahn, A. Bouvier, S. Shepard, S. Jeyarajah and I. Henderson. ISPP 2001, Orlando, FL, November, 11-14, 2001.
150. **Biophysical Characterization and Preformulation Development of a Heavy Chain Fragment of Botulinum Serotype B for Vaccine Development.** Bedu-Addo, F.K., C. Johnson, S. Jeyarajah, J. Chapline, S.R. Shepard, R. Boerner, I. Henderson, S. Advant. AAPS Meeting, Denver, CO, October 21-25, 2001.
151. **Formulation Development of Recombinant PEGylated Staphylokinase SY161 Using Statistical Design.** Bedu-Addo, F.K., R. Moreadith and S. Advant. 16th Annual Meeting of the American Association of Pharmaceutical Scientists, Denver, CO, October 2001.
152. **Biophysical Characterization and Preformulation Development of a Heavy Chain Fragment of Botulinum Serotype B for Vaccine Development.** Bedu-Addo, F.K., C. Johnson, I. Henderson and S. Advant. 16th Annual Meeting of the American Association of Pharmaceutical Scientists, Denver, CO, October 2001.

153. **Characterization of Recombinant Heavy Chain Fragments of Botulinum Neurotoxin, Serotype A and B.** Boerner, R., J. Chapline J. Ahn, A. Bouvier, S. Shepard, S. and Jeyarajah S. Henderson, ISPPP, 2001.
154. **Formulation Development of Recombinant PEGylated Staphylokinase SY161 Using Statistical Design.** Bedu-Addo, F.K., G. Conn, M. Royal, R. Moreadith and S.J. Advant. 16th Annual AAPS Meeting, October 2001.
155. **cIEF Analysis of Structural Changes of a Recombinant Vaccine During Process Development.** Jeyarajah, S., J. Chapline, J. Ahn, A. Bouvier, S. Shepard, I. Henderson, I. and R. Boerner. CEPHarm Meeting. CE in the Biotechnology and Pharmaceutical Industries: Practical Applications for the Analysis of Proteins, Nucleotides and Small Molecules, Boston, MA, August 19-21, 2001.
156. **Large Scale Expanded Bed Adsorption From Yeast Fermentation: A Case Study.** Liten, A. and S. Shepard. EBA and cGMP Biopharmaceutical Production Conference. Shanghai, China, 5-6 July 2001; Taipei, Taiwan, 9 July 2001; Bangkok, Thailand, 10 July 2001; Singapore 11-12 July 2001; Mumbai, India, July 13, 2001.
157. **Lyophilization of Protein Pharmaceuticals: A Case Study.** Bedu-Addo, F.K. 1st Barnett International Conference on Lyophilization for the Pharmaceutical and Biotechnology Industries, Philadelphia, April 25, 2001.
158. **Downstream Processing of Recombinant Proteins in the Biopharmaceutical Industry.** Shepard, S.R., ISPE Fall Seminars, Durham, N.C. September 11-12, 2000.
159. **Purification and Structural Characterization of Human Skeletal Troponin I from *Escherichia coli*.** Zhang, C., B. Reardon, X. Zeng, M. Royal, D. Brown, S. Cook, C. Lawton, and G. Conn. 14th Annual Symposium of the Protein Society, San Diego, CA, August 5-9, 2000.
160. **Structural and Functional Characterization of PEGylated Recombinant Staphylokinase.** Royal, M., C. Layton, S. Rabideau, R. Moreadith, M. Wan and G. Conn. HPLC, Seattle, WA, June 24-30, 2000.
161. **Routine Manufacture of Recombinant Proteins using Expanded Bed Adsorption Chromatography.** Shepard, S.R, G. Boyd and J. Schrimsher. EBA, Garmish-Partenkirchen, Germany, May 14-16, 2000.
162. **Purification of PEGylated Staphylokinase SY161 for Therapeutic Application.** Wan, M., Y. Wang, S. Rabideau, R. Moreadith, J. Schrimsher and G. Conn. 219th Meeting, American Chemical Society, San Francisco, CA, March 2000.
163. **Large-scale Expanded Bed Adsorption Chromatographic Purification of Recombinant Human Endostatin and Angiostatin from *Pichia pastoris* Fermentation Broth.** Shepard, S.R, G. Boyd, B. Boucher, A. Allen, J. Johnston, J. Chapline, R. Boerner, G. Koch and J. Schrimsher. American Chemical Society National Meeting, San Francisco, CA, March 26-30, 2000.

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164. **Determining Molecular Size is Straight-forward. Right? A Case Study in the Biochemical and Biophysical Characterization of a 10 kDa Recombinant Protein.** G.W. Adams, S. Sondek, J.F. Chapline, P.C. Campbell, S.J. Advant, C.B. Mendoza and E.H. Braswell. 4th Symposium on the Analysis of Well Characterized Biotechnology Biopharmaceuticals. January 9-12, San Francisco, CA, 2000.
165. **Characterization of Recombinant Angiostatin Protein from *Pichia pastoris*.** Johnston, J., T. Brown, R. Boerner, Y. Lu, D. Grella, J.W. Madsen, H. Liang and B.K.L. Sim. WCBP, San Francisco, CA, 2000.
166. **Characterization of Recombinant Endostatin Purified from *Pichia pastoris*.** Boerner, R, T. Brown, G. Adams, X.-H. Zhou, J.W. Madsen and B.K.L. Sim. WCBP, Washington, D.C., 1999.
167. **Structural Characterization of a Disulfide Crosslinked Protein Chimera by Sulfitolysis and Ion Trap Mass Spectrometry.** Brown, T., R. Boerner, S. Sondek, O. Lamm, R. Uhing, S. Advant and G. Conn. Innovations in Development Sciences, Princeton, NJ, March 2, 1998.

PRESENTATIONS (GENERAL)

1. **Process Control and Risk Assessment Management.** Moore, C. 3rd Annual Biofilm Networking Group Conference. BTEC, Raleigh, NC. November 10, 2009.
2. **Biofilm Prevention: Control by Design.** Clontz, L. 3rd Annual Biofilm Networking Group Conference. BTEC, Raleigh, NC. November 10, 2009.
3. **Strategy Discussion Forum Panelist for Tech Transfer Across the Atlantic: Charting Regulatory Course Through These Waters.** McNaull, S. BioProcess International Conference & Exhibition. Raleigh, NC. October 16, 2009.
4. **Strategy Discussion Forum Moderator for Navigating the Pathway to Regulatory Approval from Phase I to PAI.** Simon, K. BioProcess International Conference & Exhibition. Raleigh, NC. October 16, 2009.
5. **Facility Optimization: Experience of a Custom Contract Manufacturer from Broad Scope to the Details.** Wheat, J. BioProcess International Conference & Exhibition. Raleigh, NC. October 14, 2009.
6. **Strategy Discussion Forum Panelist Member for Plant Capacity: Successful Strategies to Deal with Too Much of It.** Wheat, J. BioProcess International Conference & Exhibition. Raleigh, NC. October 13, 2009.
7. **Site-to-Site Tech Transfer for Downstream Biopharmaceutical Processing: A Look into the Requirements for a Successful Process Transfer from an External Client into a CMO Facility.** Patton, K. BioProcess International Conference & Exhibition. Raleigh, NC. October 12, 2009.
8. **ASQ Certification Exams: Test Taking Tips and Tricks.** Easterly, M.C. American Society for Quality's Quality in the Triangle Conference, Raleigh, NC. May 12, 2009.
9. **Thinking Tools for Kids.** Easterly, M.C. Partners for the Advancement of Gifted Education Super Saturday. Cary, NC. April 18, 2009.
10. **Thinking Tools for Kids.** Rabideau, S. Partners for the Advancement of Gifted Education Super Saturday. Cary, NC. April 18, 2009.
11. **Facility Controls.** Clontz, L. Class for Product/Process Validation Course (PHSC 338 & 508) at Campbell University School of Pharmaceutical Sciences. Buies Creek, NC. January 28, 2009.
12. **Biopharmaceutical Industry Overview.** Clontz, L. Class for Product/Process Validation Course (PHSC 338 & 508) at Campbell University School of Pharmacy. Buies Creek, NC. January 12, 2009.
13. **The Quality Systems Approach to Internal Audits and Inspections.** Easterly, M.C. International Pharmaceutical Academy – Conducting Internal Audits Course. Montreal, Canada. October 3, 2008.

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14. **Conducting the Internal Audit – Steps and Procedures.** Easterly, M.C. International Pharmaceutical Academy – Conducting Internal Audits Course. Montreal, Canada. October 2, 2008.
15. **Microbial Limits and Bioburden Tests** (*a course presenting highlights of chapters in the 2nd edition of the book Microbial Limit and Bioburden Testing: Validation Approaches and Global Requirements*). Clontz, L. National Pharmaceutical Science Group. Montreal, Canada. September 30, 2008.
16. **Microbial Limits and Bioburden Tests** (*a course presenting highlights of chapters in the 2nd edition of the book Microbial Limit and Bioburden Testing: Validation Approaches and Global Requirements*). Clontz, L. National Pharmaceutical Science Group. Montreal, Canada. September 30, 2008.
17. **Development and Scale Up of Protein Production Using the Baculovirus Expression System.** Parekh, D. Baculovirus Technology Conference. Boston, MA. September 17-18, 2008.
18. **Cleaning Monitoring Strategies in a Biopharmaceutical Contract Manufacturing Facility.** Moore, C. IVT's Cleaning Validation and Critical Cleaning Processes Conference. Chicago, IL. July 14-17, 2008.
19. **Reducing Risk by Using a CMO: A Win-Win Situation.** Simon, K.D. IBC's 4th Annual Outsourcing Manufacturing of Biopharmaceuticals Conference. San Diego, CA. March 10-11, 2008.
20. **Risk Management for Evaluating Suppliers in the FDA-Regulated Industry.** Easterly, M.C. American Society for Quality, Customer-Supplier Relationship Symposium. Durham, NC. February 29, 2008.
21. **Qualifying Suppliers.** Easterly, M.C. Institute for Supply Management. McKimmon Center, Raleigh, NC. January 8, 2008.
22. **Reducing Cost-of-Goods for Commercial Products by Design Space Analysis.** Koch, G. Bioprocess International Conference. Boston, MA. October 1-4, 2007.
23. **Adventures with Antibodies: Diving off the Deep End of the Platform.** Bazemore, L.R. IBC: BioProcess International Conference. Boston, MA. October 1-4, 2007.
24. **Quality by Design for Biotechnology Products – Reality or Utopia?** Koch, G. 5th Global Regulatory CMC Scientific Symposium. Oss, The Netherlands. September 12, 2007.
25. **Internal Quality Audits and Inspections.** Easterly, M.C. Pharmaceutical Technology's Annual Conference, Philadelphia, PA. July 24-26, 2007.
26. **Process Validation: Current Status and Future Considerations.** Advant, S. AAPS National Biotechnology Conference. San Diego, CA. June 27, 2007.
27. **Barr Case Historical Review.** Carter-Hamm, B. RAC Study Group, Evening Classes, Duke University. Durham, NC. Summer 2007.

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28. **The Expression Conundrum.** Koch, G. BIO 2007. Boston, MA. May 9, 2007.
29. **Process Analytical Technology at Diosynth.** Williams, C., Boerner, R., and Gustines, R. BIO 2007 (*in-booth presentation*). Boston, MA. May 8, 2007.
30. **Managing CMC Changes during Clinical Development.** Advant, S. BioProcess International. Paris, France. April 26, 2007.
31. **Challenges in Manufacturing Multiple Bio-Manufacturing Projects.** Advant, S. PMI Group, Research Triangle Park, NC. April 11, 2007.
32. **GMP Training Requirements for a Pharmaceutical Quality System.** Easterly, M.C. IVT Conference: Implementing FDA's New Quality Systems Approach to Pharmaceutical cGMP Regulations. Philadelphia, PA. March 29, 2007.
33. **Documentation Requirements to Comply with FDA's Guidance on the Quality Systems Approach to Pharmaceutical cGMP Regulations.** Easterly, M.C. IVT Conference: Implementing FDA's New Quality Systems Approach to Pharmaceutical cGMP Regulations. Philadelphia, PA. March 28, 2007.
34. **Overview of the Biotech/Pharmaceutical Business from a Diosynth Biotechnology Perspective.** Adkins, B. Lecture: NCSU, Dept. of Microbiology, Master of Microbial Biotechnology Program. Raleigh, NC. March 19, 2007.
35. **Kepner-Tregoe Approach to Problem-Solving/Decision Making and Project Management.** Carter-Hamm, B. Organon Global Qualified Persons Conference. Swords, Ireland. December 6-8, 2006.
36. **Equipment Validation Requirements.** Snyder, J.M. Institute of Validation Technology. San Juan, Puerto Rico. June 22, 2006.
37. **Cleaning Risk Assessment – How Does ICH Q9 Apply?** Moore, C. IVT Cleaning Validation Conference. Las Vegas, NV. June 21-23, 2006.
38. **Cleaning Validation for Chromatography and Ultrafiltration Skids.** Moore, C. IVT Cleaning Validation Conference. Las Vegas, NV. June 21-23, 2006.
39. **Make Plain, Explain, Train: Training Personnel on Change Control Procedures.** Easterly, M.C. IVT: FDA Inspections Conference. London, England. September 20-23, 2005.
40. **Preparing for, Hosting, and Following Upon a FDA Inspection – Tools for Success.** Easterly, M.C. IVT: FDA Inspections Conference. London, England. September 20-23, 2005.
41. **To Document or Not to Document: Providing effective Supportive Documentation for Changes.** Easterly, M.C. IVT: Change Control Conference. London, England. September 20-23, 2005.

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42. **Implementing a Successful Process Validation Program.** Parekh, D. Barnett International Conference: Contract Manufacturing. Philadelphia, PA. May 13, 2005.
43. **Establishment of a Stability Testing Program in the Biotechnology Environment.** Patel, L. SWE, Inc.: Advances and Efficiencies in Stability Testing for the Pharmaceutical & BioTech Industry. San Diego, CA. March 7-8, 2005.
44. **How do CMOs evaluate potential clients, and how do clients evaluate CMOs – Panel Discussion.** Persmark, M. IBC: Biopharmaceutical Outsourcing, Contracting and Partnering. San Diego, CA March 7-8, 2005.
45. **Make Plain, Explain, Train: Training Personnel on Change Control Procedures.** Easterly, M.C. Institute of Validation Technology: Change Control Conference. Elizabeth, NJ. January 24-27, 2005.
46. **To Document or Not to Document: Providing Effective Supporting Documentation for Changes.** Easterly, M.C. Institute of Validation Technology: Change Control Conference. Elizabeth, NJ. January 24-27, 2005.
47. **Introduction to Contract Manufacturing.** Persmark, M. Elon College: Entrepreneurship in Biotechnology. January 13, 2005.
48. **The Role of a Contract Manufacturer During Technology Transfer.** Advant, S.J. AAPS National Biotechnology Conference. Boston, MA, 16-19 May, 2004.
49. **Perfusion versus Fed-batch fermentation, a strategic and economic analysis.** Grunsvan, W.v. Bio PharMOS Pharma and Biotech Manufacturing Outsourcing Services. Monte Carlo, Monaco, March 23-25, 2004.
50. **Analytical & Stability Considerations in Support of IND's and BLA's.** Advant, S.J. North Carolina Biotechnology Center, RTP, NC, February 16, 2004
51. **Developing, Executing, and Troubleshooting an Efficient Cleaning Validation Program in a Biotechnology Manufacturing Facility.** Johnson, A. Institute of Validation Technology: Cleaning Validation and Critical Cleaning Processes. San Francisco, CA, February 16-19, 2004.
52. **Approach for Evaluation, Technology Transfer, Development and Execution of Manufacturing Processes.** Advant, S.J. West Coast Consortium, Fremont, CA, February 3, 2004
53. **Getting a Retest Plan: Assignable Cause Determination in OOS Investigations.** Kelly, T. CPT: Analytical Method Validation Summit, Philadelphia, PA, October 21-22, 2003.
54. **How Much and When? Validation of Analytical Methods during Drug Development.** Kelly, T. CPT: Analytical Method Validation Summit, Philadelphia, PA, October 21-22, 2003.
55. **Manufacturing of Pharmaceutical Proteins by Cell Culture: Perfusion versus Batch Technology.** DiGuseppi, J. IBC: Biopharm Production Week,

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San Diego, CA, September 29-October 3, 2003.

56. **Validate Qualify, and Monitor Environmental Chambers.** Summers, W. CBI: Lab Equipment Qualification and Validation. Princeton, NJ, September 29-30 2003.
57. **Formulation Development: The Analytical Development Perspective.** Advant, S. IBC: 3rd International Strategies for Biopharmaceuticals, Philadelphia, PA, September 22-24, 2003.
58. **Conducting Pre-Approval Inspections at Contract Manufacturers.** Lee, K. IBC: Scaling-up from Bench to Clinic & Beyond, Research Triangle Park, August 4-6, 2003.
59. **Analytical and Stability Considerations in Support of IND's and BLA's.** Advant, S. IBC's Scaling-up from Bench to Clinic & Beyond, Research Triangle Park, August 4-6, 2003.
60. **Quality Philosophy, Organization, Roles and Responsibilities.** Patterson, D. IBC: Scaling-up from Bench to Clinic & Beyond, Research Triangle Park, August 4-6, 2003.
61. **Overview of Diosynth Biotechnology.** Persmark, M. IBC: Scaling-up from Bench to Clinic & Beyond, Research Triangle Park, August 4-6, 2003.
62. **Cleaning Validation.** Johnson, A.M. Barnett International, Philadelphia, PA, June 27-28, 2003.
63. **Manufacturing of pharmaceutical proteins by cell culture: Perfusion versus Batch technology.** van Eekelen, C. Manufacturing Strategies and Economics, Brussels, Belgium, June 16-17, 2003.
64. **Working with your contract manufacturer.** Hart, R. Biological Production Summit, Lyon, France, June 2-3, 2003.
65. **Qualification, Revalidation of Equipment.** Summers, W. CSSC's Lab Equipment Qualification and Validation. Philadelphia, PA. April 28-29, 2003.
66. **Quality Agreements and Why You Need One.** Patterson, D. Intephex, New York, NY, March 31-April 2, 2003.
67. **Managing Client Expectations.** White, C. Intephex, New York, NY, March 31-April 2, 2003.
68. **Strategies for Ensuring Clinical and Commercial Supply for Biologics.** Hart, R. BioPharMOS, Monte Carlo, Monaco, March 26-28, 2003.
69. **Evaluation of processes before technology transfer.** Koch, G. Barnett International's Manufacturing Outsourcing, Boston, MA, March 13-14, 2003.
70. **Quality Assurance Policy.** Patterson, D. Barnett International's Manufacturing Outsourcing, Boston, MA, March 13-14, 2003.
71. **Achieving a Successful Analytical Method Transfer and Avoiding Pitfalls**

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- Along the Way.** Rajagopalan, J. Pittcon, Orlando, FL, March 9-14, 2003.
72. **When to Partner with a Biopharmaceutical Contract Manufacturing Organization.** Moorthamer, M. BioPartner, Amsterdam, The Netherlands, February 12, 2003.
73. **Streamlining Cleaning Validation Execution.** Johnson, A.M. Barnett International, Philadelphia, PA, January 29-30, 2003.
74. **Mapping an Efficient Process for Conducting APR's.** Dabliz, S. 4th Annual Product Reviews: Strategies for Compliance and Quality Improvements, Washington, DC, September 19-20, 2002.
75. **Microbiological Control.** Clontz, L. Microbiological Control and Monitoring in Aseptic Manufacturing, Charleston, SC, September 9-10, 2002.
76. **Drug Development: A Regulatory Overview.** Gaido, M. CIIT, Research Triangle Park, NC, June 4, 2002.
77. **Cleaning Validation.** Johnson, A.M. Barnett International, Philadelphia, PA, January 30-31, 2002.

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PATENTS

Title	Country	Patent Number	Filing Date	Status
Porous inorganic support material coated with an organic stationary phase, for use in chromatography, and process for its preparation	US	4415631	1983-11-15	Granted
New anti-thromboticum based on polysaccharides, method for its preparation and pharmaceutical compositions.	US	4438108	1984-03-20	Granted
Sitolacton	US	4784953	1988-11-15	Granted
Semi-synthetic preparation of human insulin	US	4840897	1989-06-20	Granted
Process for splitting off 4-unstructured uronic acid from glycosaminoglyces	US	5451668	1995-09-19	Granted
Isomerisation of equilin	US	5739363	1998-04-14	Granted
Method for the preparation of steroid derivative ketal	US	5955622	1999-09-21	Granted
Microbial 11-hydroxylation of steroids	US	6046023	2000-04-04	Granted
Process for production of Heparin	US	6232093	2001-05-15	Granted
Process for the preparation of organic azides	US	6232451	2001-05-15	Granted
Method for protein purification using aqueous two-phase extraction	US	6437101 B1	1999-05-07	Granted
Feeding Processes for Fermentation	US	6955892 B2	2005-10-18	Granted
Method for protein isolation in anoxic conditions	US	000953	2004-01-29	Granted
Methods for Removing Suspended Particles from Soluble Protein Solutions	US	6,995,246 B1	2006-02-07	Granted

PUBLISHED PATENT APPLICATIONS

Title	Country	Application Number	Filing Date	Status
Methods and Compositions for Inactivating Viruses	US	EP02/05225	11/21/2002	Pending
Purification of human troponin I	US	10/255, 244	06/05/2003	Pending
Purification of human troponin I	US	10/287, 118	07/24/2003	Pending