



A Medical Device CRO

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Certification

I certify that the information below is true and accurate.

22 October 2012

Dr. Stark blogs regularly about the medical device pre-approval process, you can read her posts at http://clinicaldevice.typepad.com/cdg_whitepapers.

Nancy J Stark, PhD—Professional History

Clinical Device Group, Inc.

Nov 1990 - present

Chicago, IL

President and Owner

- Established company in 1990, incorporated in 1997, business focus: investigations of medical devices and diagnostics.
- International customer base: 60% sales within US, 40% sales outside US.
- Four employees, several independent sub-contractors who are experts in clinical, regulatory, statistics, and biological safety of medical devices.
- Four business segments:
 - Clinical research services.
 - Biocompatibility services.
 - Training.
 - Books & productivity tools.
- Authored five books and numerous articles, designed five two-day seminars, and numerous web-based workshops.
- Hosts Clinical Device Discussion Forum, an online discussion forum for medical device pre-approval issues.
- Serves as medical device consultant to IntegReview, Ethical Review Board, Austin, Texas; August 2006 to present.
- Serves as co-chair for the US delegation to TC 194/WG 4, which wrote ISO 14155, Clinical Investigations of Medical Devices; November 2000 to present.
- Serves on the Editorial Advisory Board of Medical Device & Diagnostic Industry; April 2007 to present.
- Selected as one of 100 Notable People in the medical device industry by *Medical Device & Diagnostic Industry* (2004) June.
- Lecturer, Northwestern University School of Continuing Studies, Jan 2011 to Apr 2011.

Education and Training

- Ph.D. in Biochemistry 1975
University of Minnesota, St Paul, MN
- B.S. in Chemistry 1969
University of Nebraska, Lincoln, NE

Whitepapers

1. Stark, NJ, "Registry Studies: Just like Clinical Trials", 22 October 2012.
2. Stark, NJ, "Relationship Building in Clinical Trials", 22 January 2012.
3. Stark, NJ, "Risk-Based Monitoring — The New FDA Guidance", 13 November 2011.
4. Stark, NJ, "Literature Evaluations for Biological Safety", 27 September 2011.
5. Stark, NJ, "Clinical Trial Agreements", 2 September 2011.
6. Stark, NJ, "Registry Studies: Why and How", 20 July 2011.
7. Stark, NJ, and McLain, DE, "Medical Device Biocompatibility", 1 June 2011.
8. Stark, NJ, and Jaeger, V, "Reimbursement Strategies for New Technologies", 8 May 2011.
9. Stark, NJ, and McLain, DE, "Getting to First-in-Man Studies", 7 April 2011.
10. Stark, NJ, "ISO 14155 (2011) Good Clinical Practice for Medical Devices Is Here—It's Time to Update Your Procedures!", 27 January 2011.
11. Stark, NJ, and Johnson, K, "CDRH's 510(k) Working Group Preliminary Report—Findings 6 & 7", 25 January 2011.
12. Stark, NJ, "European Medical Device Update", 29 December 2010.
13. Stark, NJ, and Johnson, K, "CDRH's 510(k) Working Group Preliminary Report—Finding 5", 16 December 2010.
14. Stark, NJ, and Johnson, K, "CDRH's 510(k) Working Group—Findings 4(b)", 30 November 2010.
15. Stark, NJ, "CDRH's 510(k) Working Group—Findings 3 & 4(a)", 22 November 2010.
16. Stark, NJ, Johnson, K, and Radcliffe, G, "CDRH's 510(k) Working Group—Findings 1 & 2", 9 November 2010.
17. Stark, NJ, and Johnson, K, "CDRH's 510(k) Working Group Preliminary Report", 29 October 2010.
18. Stark, NJ, "Statistics for Clinical Trials", 29 October 2010.
19. Stark, NJ, "Good Monitoring Practices: US and ISO Comparison", 18 October 2010.
20. Stark, NJ, "Good Monitoring Practices—'Good Grief! What Now?'" , 12 October 2010.
21. Stark, NJ, "Good Monitoring Practices—Global Consensus", 3 October 2010.
22. Stark, NJ, "A Plan for Clinical Evaluation Reports, What Do Notified Bodies Want?", 27 September 2010.
23. Stark, NJ, "The Difficulties of Good Data Management", 13 September 2010.
24. Stark, NJ, "A Standard Development Tale: ISO/FDIS 14155 'Clinical Investigations of Medical Devices in Human Subjects—Good Clinical Practice' (2010)", 6 September 2010.

25. Stark, NJ, "ISO/FDIS 14155 'Clinical Investigations of Medical Devices in Human Subjects—Good Clinical Practice (2010)'", 24 August 2010.
26. Stark, NJ, "Keeping Study Costs under Control; Building and Managing A Realistic Budget Plan", 9 September 2010.
27. Stark, NJ, "Risk Analysis Reports and EU Clinical Trials", 27 July 2010.
28. Stark, NJ, "The Critical Role of Risk Analyses in Clinical Investigations", 13 July 2010.
29. Stark, NJ, "The Clinical Research Process", 12 July 2010.
30. Stark, NJ, "Project Management of Medical Device Trials; Taking Control of the Process", 7 July 2010.
31. Stark, NJ, "Introduction to Medical Device Regulations: EU", 23 June 2010.
32. Stark, NJ, "Study Deviations and Amendments: US and ISO", 18 June 2010.
33. Stark, NJ, "The Difficulties of Good Data Management", 17 June 2010.
34. Stark, NJ, and Thiel, R, "Why Conduct Non-Inferiority Clinical Studies, Brief Comments on Missing Data", 14 June 2010.
35. Stark, NJ, "Protecting the Rights, Safety, and Welfare of Study Subjects—Supervisory Responsibilities of Investigators", 13 May 2010.
36. Stark, NJ, "The Latest in Canadian Device Regulations", 3 May 2010.
37. Stark, NJ, "What's Involved in Data Management?", 4 March 2010.

Web Publications/Web Presentations

1. Stark, NJ, "Risk-Based Monitoring for Device Trials", Courses on CD, 26 November 2011.
2. Stark, NJ, "Introduction to ISO 14155", CDG Workshop Series, 20 August 2011.
3. Stark, NJ, "Good Monitoring Practices Workshop", CDG Workshop Series, 10 February 2010.
4. Stark, NJ, "Good Protocol Design Workshop", CDG Workshop Series, 13 January 2010.
5. Stark, NJ, "IDE Workshop", CDG Workshop Series, 16 December 2009.
6. Stark, NJ, "Registry Basics for Medical Devices", CDG e-Conference Series, 18 November 2009.
7. Stark, NJ, "The New ISO/DIS 14155 (2009)", CDG e-Conference Series, 14 October 2009.
8. Stark, NJ, "IDE Workshop", CDG Workshop Series, 19 August 2009.
9. Stark, NJ, "Ten Mistakes Monitors Manage", CDG e-Conference Series, 15 July 2009.
10. Stark, NJ, "Project Management Workshop", CDG Workshop Series, 17 June 2009.
11. Stark, NJ, "Adverse Event Workshop", CDG Workshop Series, 13 May 2009.
12. Stark, NJ, "Adverse Event Workshop", CDG Workshop Series, 15 April 2009.
13. Stark, NJ, "Quality Systems Workshop", CDG Workshop Series, 11 February 2009.
14. Stark, NJ, "Protocol Design Workshop", CDG Workshop Series, 10 December 2008.
15. Stark, NJ, "ISO/DIS 14155 (2008) Clinical Investigation of Medical Devices in Human Subjects—Good Clinical Practices", CDG e-Conference Series, 29 October 2008.

16. Stark, NJ, "Regulatory Permissions Workshop", CDG Workshop Series, 15 October 2008.
17. Stark, NJ, "Adverse Event Workshop", CDG Workshop Series, 17 September 2008.
18. Stark, NJ, "Good Monitoring Practices Workshop", CDG Workshop Series, 27 August 2008.
19. Stark, NJ, "Protocol Deviations Workshop", CDG Workshop Series, 23 July 2008.
20. Stark, NJ, "Adverse Event Workshop", CDG Workshop Series, 16 June 2008.
21. Stark, NJ, "Regulatory Permissions Workshop", CDG Workshop Series, 14 May 2008.
22. Stark, NJ, "Good Monitoring Practices Workshop", CDG Workshop Series, 7 March 2008.
23. Secic, M and Stark, NJ, "What's Special about Diagnostic Trials?" CDG e-Conference Series, 6 March 2007.
24. Stark, NJ, "Designing Paper-Based Case Report Forms" CDG e-Conference Series, 27 February 2007.
25. Schiff, K and Stark, NJ, "ISO or ICH—Which One for You?" FOI Services audio-conference, 30 August 2006.
26. Stark, NJ, "Starting in Europe", CDG e-Conference Series, July 2004.
27. Stark, NJ, "What's Up with Monitoring and the FDA?" CDG e-Conference Series, June 2004.
28. Stark, NJ, "Clinical Databases and Part 11: The Regulated Database", FOI Online, 27 June 2004.
29. Stark, NJ, "Quality Systems for Clinical Research", CDG e-Conference Series, May 2006.
30. Stark, NJ, "Survey of Clinical Research Practices in the Device Industry", January 2004.
31. Stark, NJ, "Clinical Databases and Part 11: Designing Case Report Forms", September 2003.
32. Stark, NJ, "ISO/FDSI 10993-3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity - A Manager's Quiz, July 2003.
33. Stark, NJ, "Clinical Databases and Part 11: A Beginner's Walk through Part 11", May 2003
34. Stark, NJ, "Clinical Databases and Part 11: The Regulated Database", FOI Online, April 24, 2003.
35. Stark, NJ, "Survey of Clinical Research Practices in the Medical Device Industry", January 2002.
36. Stark, NJ, "HIPPA--Security and Privacy Impact on Clinical Research", July 2002.
37. Stark, NJ, "ISO 10993--Biological Evaluation of Medical Devices: A Manager's Quiz", May 28, 2002.
38. Stark, NJ, "Predicting the Future: Clinical Research in the US", March 22, 2002.
39. Stark, NJ, "Declaration of Helsinki - Controversies with Revisions 2000", October 31, 2001.
40. Stark, NJ, "Survey of Clinical Research Practices in the Medical Device Industry", August 18, 2001.

Articles

1. Stark, NJ, "US FDA Proposals on Risk-based Clinical Trial Monitoring and Their Implications for Medical Device Manufacturers," *Regulatory Affairs Medtech*, in press.
2. Stark, NJ, "Data Management in Device Studies," *Journal of Clinical Research Best Practices*, (2011) Oct (7)10. http://www.firstclinical.com/journal/2011/1110_Data_Management.pdf.
3. Stark, NJ and McLain DE, "Medical Device Biocompatibility: Where to begin Biological Safety Testing," *Regulatory Affairs Medtech*, July/August 2011, p20.
4. Stark, NJ, "Key Revisions to Medical Device Clinical Investigations Standard ISO 14155," *Regulatory Affairs Medtech*, May/June 2011, p14.
5. Stark, NJ, "A New Standard for Medical Device Investigations", *Journal of Clinical Research Best Practices*, (2011) Feb(7)1. http://www.firstclinical.com/journal/2011/1102_ISO_14155.pdf.
6. Stark, NJ, "Keeping Device Study Costs under Control: Building a Realistic Budget", *Journal of Clinical Research Best Practices*, (2011) Jan (7)1. http://www.firstclinical.com/journal/2011/1101_Device_Budget.pdf.
7. Stark, NJ, "Clinical Evaluation Reports: The New Requirement", *Medical Device & Diagnostic Industry*, (2010) Jan (32)1, p76.
8. Stark, NJ, "A New Standard for Medical Device Adverse Event Classification", *Journal of Clinical Research Best Practices*, (2009) Dec (5)12. http://firstclinical.com/journal/2009/0912_ISO_14155.pdf.
9. Stark, NJ, and Baresch, J, "Exploring Thirty Years of Preambles", *Medical Device & Diagnostic Industry*, (2009) June (31)6 p58.
10. Stark, NJ, "Meeting US Rules on Clinical Trial Deviations", *Regulatory Affairs Journal, Devices* (2008) Nov/Dec (16) p391.
11. Stark, NJ, "Clinical Trial Deviations", *The Journal of Biolaw and Business*, (2008) Fall.
12. Gertel, A, and Stark, NJ, "The world of medical devices—serving two masters", *The Write Stuff*, (2008) June (17)2 p74.
13. Stark, NJ, "Best of Both Worlds: SOPs for Device Trials in Europe", *Regulatory Affairs Journal, Devices* (2008) Mar/April (16) p85.
14. Stark, NJ "Best of Both Worlds: SOPs for Device Trials in Europe, Part 2", *Medical Device & Diagnostic Industry*, (2007) July p82.
15. Stark, NJ "Best of Both Worlds: SOPs for Device Trials in Europe, Part 1", *Medical Device & Diagnostic Industry*, (2007) May p108.
16. Stark, NJ, "Outsourcing Clinical Research: A Comparison between the US and the EU", *Regulatory Affairs Journal, Devices* (2004) Jan/Feb p13.
17. Stark, NJ, "Outsourcing Clinical Research: A Comparison between the US and the EU", *Regulatory Affairs Journal, Devices* (2005) Jan/Feb p11.
18. Stark, NJ, "A Long Road: 25 Years of Clinical Research", *Medical Device & Diagnostic Industry*, (2004) August p96.
19. Stark, NJ, "Clinical Outsourcing in Europe", *Medical Products Outsourcing*, (2004) June p64.
20. Stark, NJ and Peacock, J, "Clinical Studies: Europe or the United States?" *Medical Device & Diagnostic Industry*, (2004) May p134.

21. Stark, NJ, "Understanding Biological Safety", *Medical Device Technology*, (2002) September 13(7) p28.
22. Stark, NJ, "Manager's Series: Biological Evaluations of Medical Devices—Part 1, Evaluation", *MedSpark*, (2002) July.
23. Stark, NJ, "HIPAA & EU data protection—the dos and don'ts of privacy", *Clinica*, (2002) June (5) p1010.
24. Stark, NJ, "Meeting the Requirements of the Personal Data Protection Directive through HIPAA Privacy Rules", *MedSpark*, (2001) Dec (1).
25. Stark, NJ and Heath, E, "Incorporating the New HIPAA Privacy Rules into Medical Device Trials", *Medical Device & Diagnostic Industry*, (2001) July, 114.
26. Stark, NJ, "Integrating Clinical Research into the Product Development Cycle", *Medical Device & Diagnostic Industry*, (2001) May, 150.
27. Stark, NJ, "Prüfzentren - Management bei klinischen Studien" *Deutsche Zeitschrift für Klinische Forschung*, (2000) August.
28. Stark, NJ, "Clinical Trials for Medical Devices, Information for Investigators" *The Monitor*, (2000) Volume 14:1, Spring.
29. Stark NJ, Rasmussen P, Spencer H, "Clinical Trial Site Management" *Global CONTACT*, (1999) Number 21:31.
30. Stark, NJ, "Managing Adverse Events and Effects during Clinical Trials" *Medical Device & Diagnostic Industry*, (1999) July: 88.
31. Stark, NJ, "Conducting Health-Based Risk Assessments of Medical Materials" *Medical Plastics and Biomaterials*, (1998) September/October, 5(5):18.
32. Stark, NJ, "Requirements for Clinical Trials for Medical Devices" *Technology News, American Medical Association*, (1997) April: 1.
33. Stark, NJ, "Using Data Obtained Overseas for FDA Approval" *Applied Clinical Trials*, (1997) September: 38.
34. Stark, NJ, "Software Can Help Manage Clinical Trials" *Medical Device & Diagnostic Industry*, (1997) April.
35. Stark, NJ, "The Clinical Research Industry: New Options for Medical Device Manufacturers" *Medical Device & Diagnostic Industry*, (1997) January: 215.
36. Stark, NJ, "Clinical Trials for Medical Devices, An Introduction" *Applied Clinical Trials*, (1997) January: 34.
37. Stark NJ, "Clinical Research for CEOs: A Guide to Good Business Practice and the Conduct of Clinical Trials", (1996) *Clinica*, 736/737:17.
38. Stark, NJ, "The Biological Safety of Nitinol: A Case Study in New Material Evaluation" *The Validation Consultant*, (1996) 3(9): 8.
39. Stark, NJ, "Managing Positive Biocompatibility Test Results", *Medical Device & Diagnostic Industry*, (1996) 18(10): 148.
40. Stark, NJ, "Introduction to Monitoring", (1996) *Applied Clinical Trials*, 5(5):34-40.
41. Stark, NJ, "Literature Report: Biological Safety of Parylene C", *Medical Plastics and Biomaterials*, (1996) 3(2): 30.
42. Stark, NJ, "Designing Clinical Trials for Business and Marketing Needs", *The Booth Validator*, (1995) 2(1): 3.

43. Stark, NJ, "Documenting Test Material Characterization", *Medical Plastics and Biomaterials*, (1994) 1(2): 50-55.
44. Stark, NJ, "Biocompatibility Management: A Quality System for Biological Safety", *Medical Device & Diagnostic Industry*, (1994) 16(3):92-100.
45. Stark, NJ, "Standard Operating Procedures and Biological Safety Testing", *Medical Device & Diagnostic Industry*, (1994) 16(5):238-242.
46. Stark, NJ, "How to Reorganize a Clinical Research Department", *Medical Device & Diagnostic Industry*, (1992) 14(6):154-159.
47. Stark, NJ, "A Chemist's View of Biocompatibility", *Medical Device & Diagnostic Industry*, (1991) 13(5):86-93.
48. Stark, NJ, "How to Organize a Biocompatibility Testing Program: A Case Study", *Medical Device & Diagnostic Industry*, (1991) 13(6):68-75.
49. Stark, NJ, "A Context for Clinical Research" (guest editorial), *Medical Device & Diagnostic Industry*, (1986) 8:10.

Academic Research

1. Stark NJ, Levy GN, Rohr TE, Anderson JS, "Reactions of Second Stage of Biosynthesis of Teichuronic Acid of *Micrococcus lysodeikticus* Cell Walls", *The Journal of Biological Chemistry*, (1977) May (252):10 p3466.
2. Rohr TE, Levy GN, Stark NJ, Anderson JS, "Initial Reactions in Biosynthesis of Teichuronic Acid of *Micrococcus lysodeikticus* Cell Walls", *The Journal of Biological Chemistry*, (1977) May (252):10 p3460.

Books

1. Stark, NJ, *Clinical Research Quality System, Fourth Edition* (1996, 2001, 2006, 2009), Clinical Device Group Inc, Chicago, IL.
2. Stark, NJ, *Clinical Trials Design: Evaluation for Medical Devices, Second Edition* (2002), Kyung Hee University Press, Seoul, Korea. (Translation into Korean arranged by Duran Kim Agency, Seoul, Korea, 2010.)
3. Stark, NJ, *Clinical Trials Design: Evaluation for Medical Devices, Second Edition* (2002), Scientist Inc. Sha, Tokyo, Japan. (Translation into Japanese arranged by A. Nakamura et al. Japan Uni Agency, Tokyo, Japan, 2004.)
4. Stark, NJ, *Biocompatibility Testing & Management*, (1992, 1996, 1998, 2003), Clinical Device Group Inc, Chicago, IL.
5. Stark, NJ, *Clinical Trials Design*, (1996, 2000, 2002) Clinical Device Group Inc, Chicago, IL.
6. Stark, NJ, *Project Management*, (1999, 2003), Clinical Device Group Inc, Chicago, IL.
7. Stark, NJ, *Applied Regulations*, (2002, 2004) Clinical Device Group Inc, Chicago, IL.
8. Stark, NJ, *Good Monitoring Practices*, (1996, 1999, 2004) Clinical Device Group Inc, Chicago, IL.
9. Stark, NJ, *CRA Handbook* (1995, 1998, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009) Clinical Device Group Inc, Chicago, IL.

10. Stark, NJ, *Investigator's Guide to Clinical Research* (2002) Clinical Device Group Inc, Chicago, IL.
11. Stark, NJ, *Investigator Handbook: On-Site Organization and Management* (1997) Clinical Device Group Inc, Chicago, IL.
12. Stark, NJ, Editor, *US Guidances for Clinical Research* (2002, 2005, 2007, 2008, 2009), Clinical Device Group Inc, Chicago, IL.
13. Stark, NJ, Editor, *Europe Laws, Second Edition* (2002, 2005) Clinical Device Group Inc, Chicago, IL.
14. Stark, NJ, *International Clinical Trials, Third Edition* (1996, 1998) Clinical Device Group Inc, Chicago, IL.

Invited Lectures

1. Stark, NJ, "Introduction to Medical Device Clinical Trials", Northwestern University, 8 March 2010.
2. Stark, NJ, "Clinical Trials: What to Do and How to Do It", MDM Rosemont Conference & Exhibition, Rosemont, IL, 24 September 2009.
3. Stark, NJ, "Medical Device Adverse Events", Global ACRP Meeting, Seattle, WA, 22 April 2007.
4. Stark, NJ, "From Claims to Protocols", Regional RAPS Meeting, Chicago, IL, 29 September 2005.
5. Stark, NJ, "Project Management for Medical Device Trials", two-day training at MedicoIndustrien, Copenhagen, Denmark, 15-16 September 2005.
6. Stark, NJ, "Biocompatibility Testing & Management", two-day training at MedicoIndustrien, Copenhagen, Denmark, 13-14 September 2005.
7. Stark, NJ, "From Claims to Clinicals: How Claims Set the Specifications for Your Protocol", 2nd Meeting of Japan Forum of Clinical Trials on Medical Devices, 3 September 2005, Tokyo, Japan.
8. Stark, NJ, "European Medical Device Regulation", three-day training at FDA/CDRH, Washington, DC. 13-15 July 2005.
9. Stark, NJ, "A Comparison of ISO 14155 and the ICH-GCPs", Barnett/Paraxel Summit on Drug and Device Safety, 4 May 2005, Philadelphia, MD.
10. Stark, NJ, "Data Management for Medical Devices: Confusion and Controversy", DIA Data Management Conference, 9 November 2004, Amsterdam, The Netherlands.
11. Stark, NJ, "Device Clinical Trials in the European Union", FDA/CDRH College, 27 April 2004, Rockville, MD.
12. Stark, NJ, "Clinical Research Practices in the Device Industry," Center for Business Intelligence conference on Pre-clinical and Clinical Trials for Medical Device and Combination Products, 11-12 March 2004, Minneapolis, MN.
13. Stark, NJ, "Regulated Databases: Navigating Computerized Systems Used in Clinical Trials", Center for Business Intelligence conference on Pre-clinical and Clinical Trials for Medical Device and Combination Products, 11-12 March 2004, Minneapolis, MN.
14. Stark, NJ, "Project Management for Clinical Research," ASQ New England, 18 November 2003, Needham, MA.

15. Stark, NJ, Keynote Address: "Clinical Research Practices in the Device Industry", ASQ New England, 18 November 03, Needham, MA.
16. Stark, NJ, "Basic Aspects and Principal Problems in the Management of a Clinical Study", DIA Second Latin American Congress of Clinical Research, 29 September-1 October 2003, Mexico City, Mexico.
17. Stark, NJ, "Clinical Databases and Part 11: The Regulated Database", Orange County Regulatory Affairs Society, 4-5 June 2003, Irvine, CA.
18. Stark, NJ, "Clinical Databases and Part 11: A Layman's Primer to System Documentation", DIA Device Conference, 24-25 February 2003, San Francisco, CA.
19. Stark, NJ, "Closing Plenary—Predicting the Future of Clinical Research: New Government Initiatives that Impact Clinical Trials", RAPS Clinical Trials Conference, 5-6 August 2002, Washington, DC.
20. Stark, NJ, "HIPAA Requirements and Their Effect on Clinical Research", RAPS Clinical Trials Conference, 5-6 August 2002, Washington, DC.
21. Stark, NJ, "Predicting the Future: Clinical Research in the United States", SoCRA, Minnesota Local Chapter, 13 June 2002, Minneapolis, MN.
22. Stark, NJ, "HIPAA—Health Insurance Portability and Accountability Act", SoCRA, Minnesota Local Chapter, 13 June 2002, Minneapolis, MN.
23. Stark, NJ, "HIPAA—Health Insurance Portability and Accountability Act", FDA/OCRA Educational Conference, 3-4 June 2002, Irvine, CA.
24. Stark, NJ, "Case Study: Dulcé Devices Implementing ISO EN 14155-1 & 2", AAMI/FDA International Conference on Medical Device Standards and Regulation, 27-28 March 2002, McLean, VA.
25. Stark, NJ, "Current US Regulatory and Ethical Issues in Clinical Research", Regulatory Affairs Professionals Society, 20 March 2002, San Francisco, CA.
26. Stark, NJ, "Investigator Selection & Clinical Study Monitoring", Medical Alley, 20 February 2002, St. Paul, MN.
27. Stark, NJ, "Survey of Clinical Research Practices: Medical Device Industry", Biomedical Focus, 18 July 2001, St. Paul, MN.
28. Stark, NJ, "Current Topics in Clinical Research", Biomedical Focus, 18 July 2001, St. Paul, MN.
29. Stark, NJ, "Device Clinical Trials in the European Union", FDA/CDRH College, 21 June 2001, Rockville, MD.
30. Stark, NJ, "Current Topics in Clinical Research", Medical Design & Manufacturing East, 5 June 2001, New York, NY.
31. Stark, NJ, "Clinical Trials for Medical Devices", Regulatory Affairs Professionals Society, 2-4 October 2000, Washington, DC.
32. Stark, NJ, "Managing Subject Risk in Device Trials", Association of Clinical Research Professionals, 15-17 May 2000, New Orleans, LA.
33. Stark, NJ, "Project Management: A Case Study," Institute for International Research Conference on Project Management for Research & Development and Clinical Research, 23-25 February 2000, Philadelphia, PA.
34. Stark, NJ, "Clinical Trial Site Management", Association of Clinical Research Professionals, 21-24 April 1999, Washington, DC.

35. Stark, NJ, "Clinical Trial Site Management", Biomedical Focus, 20-22 July 1998, Minneapolis, MN.
36. Stark, NJ, "Working with CROs", Biomedical Focus, 20-22 July 1998, Minneapolis, MN.
37. Stark, NJ, "Health-Based Risk Assessments", Biomedical Focus, 20-22 July 1998, Minneapolis, MN.
38. Stark, NJ, "Case Studies: Material Safety Reviews", Medical Design & Manufacturing East97, 1-5 June 97, New York, NY.
39. Stark, NJ, "Using Foreign Clinical Data in US Submissions", International Business Communications Conference, 15-16 August 1996, Williamsburg, VA.
40. Stark, NJ, "Managing Positive Biological Safety Result", Biomedical Focus X, 15-17 July 1996, Minneapolis, MN.
41. Stark, NJ, "The Changing Clinical Research Industry: A Challenge for the Future", Biomedical Focus X, 15-17 July 1996, Minneapolis, MN.
42. Stark, NJ, "Managing Positive Biological Safety Results", Medical Design and Manufacturing West, 6-8 February 1996, Anaheim, CA.
43. Stark, NJ, "Policies of Quality and Management in Cosmetic Dermatology", International Society of Cosmetic Dermatology, 26 October 1995, Montecatini Terme, Italy.
44. Stark, NJ, "Solving Quality Problems in Biocompatibility Management", Session Chair, Medical Design and Manufacturing East, 24-26 May 1994, New York City, NJ.
45. Stark, NJ, "Identity Documentation for Materials", Medical Design and Manufacturing East, 24-26 May 1994, New York City, NJ.
46. Stark, NJ, "Materials and Surveillance Screening—Why and How", Medical Design and Manufacturing East, 25-27 May 1993, New York City, NY.
47. Stark, NJ, "Biological Safety: Design and Planning Issues", Biomedical Focus VI Conference and Exposition, 27-29 July 1992, Bloomington, MN.
48. Stark, NJ, "Materials Screening—Why and How", Medical Design and Manufacturing West, 4-6 February 1992, Anaheim, CA.

Session Chairs

1. "Pre-clinical and Clinical Trials for Medical Device and Combination Products, Center for Business Intelligence, 11-12 March 2004, Minneapolis, MN.
2. "Biocompatibility Workshop", Roche Diagnostics, 20-21 December 1999, Indianapolis, IN.
3. "Trends in Biocompatibility Standards" Medical Design & Manufacturing, 4-6 November 1997.
4. "Overseeing Your Overseas Clinical Trials" Medical Design & Manufacturing East97, 1-5 June 1997, New York, NY.
5. "A New Approach to Material Biocompatibility Testing" Medical Design & Manufacturing East97, 1-5 June 1997, New York, NY.
6. Medical Device Track Chair, Association of Clinical Research Professionals Annual Conference, 18-21 May 1997, Atlanta, GA.

Professional Appointments

1. ANSI Technical Committee 232 on international standards for continuing education and training.

2. Editorial Advisory Board, Medical Device & Diagnostic Industry, Canon Communications (2007-present).
3. Medical device consultant for IntegReview IRB (2007-present).
4. Co-Chair of ISO Technical Committee 194, Working Group 4 on international standards for clinical investigations of medical devices (2000-present).
5. Editorial Advisory Board: The Monitor (publication of the Association of Clinical Research Professionals) (2001-present).
6. AAMI/ISO Technical Advisory Group 194 (ISO 10993 standards) (1998-present).
7. AAMI/ISO Technical Committee 212 (In vitro diagnostic standards) (2000-present).
8. Advisory Board: International Society of Cosmetic Dermatologists (1997-1999).
9. Medical Device Forum Chair: Association of Clinical Research Professionals (1997-1999).
10. Editorial Advisory Board: The Validation Consultant (1998-2000).
11. Editorial Advisory Board: Medical Plastics & Biomaterials (1996-1998).

Professional Memberships

1. Society of Biomaterials.
2. American Association of Medical Instrumentation (AAMI).
3. American College of Toxicology.
4. Controlled Release Society.
5. Regulatory Affairs Professional Society (RAPS).
6. Association of Clinical Research Professionals (ACRP).
7. Society for Clinical Trials.
8. Society for Clinical Research Associates (SoCRA).
9. American Association of Clinical Chemistry (AACC).
10. National Council for Continuing Education and Training (NCCET).

Employment History

Hollister Incorporated

Jan 1985 - Nov 1990

Libertyville, IL

Manager, Medical Affairs

- Managed a \$500,000 annual budget and four Clinical Research Associates.
- Organized a methodical and IDE compliant system of conducting clinical research. Managed over 30 clinical trials per year.
- Organized compliant system for in-house panel testing of products on employee volunteers.
- Designed and implemented a rational system of biocompatibility testing. This system saved the company \$50,000 annually in safety testing.
- Designed and implemented a computer application for storing and retrieving biocompatibility test data.
- Authored a training manual for conducting safety and efficacy testing. The manual became corporate policy.
- Supervised clinical research trials in the following areas: IV infusion therapy, wound care, ostomy care, circumcision, and clinical diagnostics.

3M Company

May 1980 - Jan 1985

St. Paul, MN

Supervisor, Clinical Research

Sr. Clinical Research Associate

- Supervised a staff of ten Clinical Research Associates
- Supervised extensive in-house evaluation program of dermal contact products; two technicians conducted more than 100 panels each year.
- Developed division policy for specifying safety and efficacy data required to support new product claims.
- Designed computer application for archiving and retrieving clinical research data.
- Conducted clinical research trials in the following areas: ECG/EKG electrodes, medical tapes, transparent wound dressings, biological indicators for ethylene oxide and steam sterilization monitoring, stethoscopes, TENS electrodes and stimulators, and I-125 Seeds for brachytherapy.