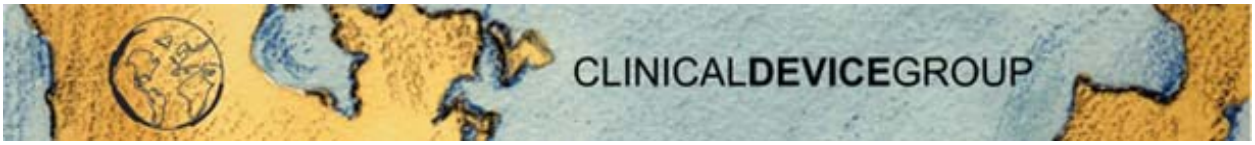

Consulting, Contracting, and Training for Medical Device Manufacturers

Clinical Device Group
2128 W. Evergreen Ave.
Floor One
Chicago, IL 60622

Phone 773/489-5721
Fax 773/489-4281
njstark@clinicaldevice.com
www.clinicaldevice.com

Certification

I certify that the information below is true and accurate.

27 October 09

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: evaluations of medical devices and diagnostics.
- International customer base: 60% sales within US, 40% sales outside US.
- Four employees, seven regular sub-contractors in with skills in monitoring, regulatory, statistics, and biological safety.
- Four business segments:
  - Clinical research services.
  - Biocompatibility services.
  - On-site and public seminars.
  - 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.

Education and Training

Ph.D. in Biochemistry 1975
University of Minnesota, St Paul, MN

B.S. in Chemistry 1969

University of Nebraska, Lincoln, NE

Web Publications / Web Presentations

1. Stark, NJ, “IDE Workshop”, CDG Workshop Series, 19 August 2009.
2. Stark, NJ, “Ten Mistakes Monitors Manage”, CDG e-conference Series, 15 July 2009.
3. Stark, NJ, “Project Management Workshop”, CDG Workshop Series, 17 June 2009.
4. Stark, NJ, “Adverse Event Workshop”, CDG Workshop Series, 13 May 2009.
5. Stark, NJ, “Adverse Event Workshop”, CDG Workshop Series, 15 April 2009.
6. Stark, NJ, “Quality Systems Workshop”, CDG Workshop Series, 11 February 2009.
7. Stark, NJ, “Protocol Design Workshop”, CDG Workshop Series, 10 December 2008.
8. Stark, NJ, “ISO/DIS 14155 (2008) Clinical Investigation of Medical Devices in Human Subjects—Good Clinical Practices”, CDG e-conference Series, 29 October 2008.
9. Stark, NJ, “Regulatory Permissions Workshop”, CDG Workshop Series, 15 October 2008.
10. Stark, NJ, “Adverse Event Workshop”, CDG Workshop Series, 17 September 2008.
11. Stark, NJ, “Good Monitoring Practices Workshop”, CDG Workshop Series, 27 August 2008.
12. Stark, NJ, “Protocol Deviations Workshop”, CDG Workshop Series, 23 July 2008.
13. Stark, NJ, “Adverse Event Workshop”, CDG Workshop Series, 16 June 2008.
14. Stark, NJ, “Regulatory Permissions Workshop”, CDG Workshop Series, 14 May 2008.
15. Stark, NJ, “Good Monitoring Practices Workshop”, CDG Workshop Series, 7 March 2008.
16. Secic, M and Stark, NJ, “What’s Special about Diagnostic Trials?” CDG e-conference Series, 6 March 2007.
17. Stark, NJ, “Designing Paper-Based Case Report Forms” CDG e-conference Series, 27 February 2007.
18. Schiff, K and Stark, NJ, “ISO or ICH—Which One for You?” FOI Services audio-conference, 30 August 2006.
19. Stark, NJ, “Starting in Europe”, CDG e-conference Series, July 2004.
20. Stark, NJ, “What’s Up with Monitoring and the FDA?” CDG e-conference Series, June 2004.
21. Stark, NJ, “Clinical Databases and Part 11: The Regulated Database”, FOI Online, 27 June 2004.
22. Stark, NJ, “Quality Systems for Clinical Research”, CDG e-conference Series, May 2006.
23. Stark, NJ, “Survey of Clinical Research Practices in the Device Industry”, January 2004.
24. Stark, NJ, “Clinical Databases and Part 11: Designing Case Report Forms”, September 2003.
25. Stark, NJ, "ISO/FDSI 10993-3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity - A Manager's Quiz, July 2003.
26. Stark, NJ, “Clinical Databases and Part 11: A Beginner’s Walk through Part 11”, May 2003

27. Stark, NJ, “Clinical Databases and Part 11: The Regulated Database”, FOI Online, April 24, 2003.
28. Stark, NJ, "Survey of Clinical Research Practices in the Medical Device Industry", January 2002.
29. Stark, NJ, "HIPPA--Security and Privacy Impact on Clinical Research", July 2002.
30. Stark, NJ, "ISO 10993--Biological Evaluation of Medical Devices: A Manager's Quiz", May 28, 2002.
31. Stark, NJ, "Predicting the Future: Clinical Research in the US", March 22, 2002.
32. Stark, NJ, "Declaration of Helsinki - Controversies with Revisions 2000", October 31, 2001.
33. Stark, NJ, "Survey of Clinical Research Practices in the Medical Device Industry", August 18, 2001.

Articles

1. Stark, NJ, and Baresch, J, “Exploring Thirty Years of Preambles”, *Medical Device & Diagnostic Industry,* (2009) June:31:6 p58.
2. Stark, NJ, “Meeting US Rules on Clinical Trial Deviations”, *Regulatory Affairs Journal, Devices* (2008) Nov/Dec:16 p391.
3. Stark, NJ, “Clinical Trial Deviations”, *The Journal of Biolaw and Business*, (2008) Fall.
4. Gertel, A, and Stark, NJ, “The world of medical devices—serving two masters”, *The Write Stuff*, (2008) 17:2 p74.
5. Stark, NJ, “Best of Both Worlds: SOPs for Device Trials in Europe”, *Regulatory Affairs Journal, Devices* (2008) Mar/April:16 p85.
6. Stark, NJ “Best of Both Worlds: SOPs for Device Trials in Europe, Part 2”, *Medical Device & Diagnostic Industry*, (2007) July p 82.
7. Stark, NJ “Best of Both Worlds: SOPs for Device Trials in Europe, Part 1”, *Medical Device & Diagnostic Industry*, (2007) May P108.
8. Stark, NJ, “Outsourcing Clinical Research: A Comparison between the US and the EU”, *Regulatory Affairs Journal, Devices* (2004) Jan/Feb: 13.
9. Stark, NJ, “Outsourcing Clinical Research: A Comparison between the US and the EU”, *Regulatory Affairs Journal, Devices* (2005) Jan/Feb p 11.
10. Stark, NJ, “A Long Road: 25 Years of Clinical Research”, *Medical Device & Diagnostic Industry,* (2004) August: 96.
11. Stark, NJ, “Clinical Outsourcing in Europe”, *Medical Products Outsourcing,* (2004) June: 64.
12. Stark, NJ and Peacock, J, “Clinical Studies: Europe or the United States?” *Medical Device & Diagnostic Industry,* (2004) May: 134.
13. Stark, NJ, “Understanding Biological Safety”, *Medical Device Technology,* (2002) September, Volume 13(7): 28.
14. Stark, NJ, “Manager’s Series: Biological Evaluations of Medical Devices—Part 1, Evaluation”, *MedSpark,* (2002) July.

15. Stark, NJ, “HIPAA & EU data protection—the dos and don’ts of privacy”, *Clinica*, (2002) June 5:1010.
16. Stark, NJ, “Meeting the Requirements of the Personal Data Protection Directive through HIPAA Privacy Rules”, *MedSpark,* (2001) Dec: 1.
17. Stark, NJ and Heath, E, “Incorporating the New HIPAA Privacy Rules into Medical Device Trials”, *Medical Device & Diagnostic Industry,* (2001) July: 114.
18. Stark, NJ, “Clinical Research in the Product Development Cycle”, *Medical Device & Diagnostic Industry*, (2001) May: 150.
19. Stark, NJ, “Prufzentren - Management bei klinischen Studien” Deutsche Zeitschrift fur Klinische Forschung, (2000) August.
20. Stark, NJ, “Clinical Trials for Medical Devices, Information for Investigators” *The Monitor*, (2000) Volume 14:1, Spring.
21. Stark NJ, Rasmussen P, Spencer H, “Clinical Trial Site Management” *Global CONTACT,* (1999) Number 21:31.
22. Stark, NJ, “Managing Adverse Events and Effects during Clinical Trials” *Medical Device & Diagnostic Industry*, (1999) July: 88.
23. Stark, NJ, “Conducting Health-Based Risk Assessments of Medical Materials” *Medical Plastics and Biomaterials,* (1998) September/October, 5(5):18.
24. Stark, NJ, “Requirements for Clinical Trials for Medical Devices” *Technology News, American Medical Association,* (1997) April: 1.
25. Stark, NJ, “Using Data Obtained Overseas for FDA Approval” *Applied Clinical Trials,* (1997) September: 38.
26. Stark, NJ, “Software Can Help Manage Clinical Trials” *Medical Device & Diagnostic Industry,* (1997) April.
27. Stark, NJ, “The Clinical Research Industry: New Options for Medical Device Manufacturers” *Medical Device & Diagnostic Industry*, (1997) January: 215.
28. Stark, NJ, “Clinical Trials for Medical Devices, An Introduction” *Applied Clinical Trials,* (1997) January: 34.
29. Stark NJ, “Clinical Research for CEOs: A Guide to Good Business Practice and the Conduct of Clinical Trials”, (1996) *Clinica,* 736/737:17.
30. Stark, NJ, “The Biological Safety of Nitinol: A Case Study in New Material Evaluation” *The Validation Consultant,* (1996) 3(9): 8.
31. Stark, NJ, “Managing Positive Biocompatibility Test Results”, *Medical Device & Diagnostic Industry,* (1996) 18(10): 148.
32. Stark, NJ, “Introduction to Monitoring”, (1996) *Applied Clinical Trials,* 5(5):34-40.
33. Stark, NJ, “Literature Report: Biological Safety of Parylene C”, *Medical Plastics and Biomaterials,* (1996) 3(2): 30.
34. Stark, NJ, “Designing Clinical Trials for Business and Marketing Needs”, *The Booth Validator,* (1995) 2(1): 3.
35. Stark, NJ, “Documenting Test Material Characterization”, *Medical Plastics and Biomaterials,* (1994) 1(2): 50-55.
36. Stark, NJ, “Biocompatibility Management: A Quality System for Biological Safety”, *Medical Device & Diagnostic Industry,* (1994) 16(3):92-100.

37. Stark, NJ, "Standard Operating Procedures and Biological Safety Testing", *Medical Device & Diagnostic Industry,* (1994) 16(5):238-242.

38. Stark, NJ, "How to Reorganize a Clinical Research Department", *Medical Device & Diagnostic Industry,* (1992) 14(6):154-159.

39. Stark, NJ, "A Chemist's View of Biocompatibility", *Medical Device & Diagnostic Industry*, (1991) 13(5):86-93.

40. Stark, NJ, "How to Organize a Biocompatibility Testing Program: A Case Study", *Medical Device & Diagnostic Industry*, (1991) 13(6):68-75.

41. Stark, NJ, "A Context for Clinical Research" (guest editorial), *Medical Device & Diagnostic Industry*, (1986) 8:10.

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), Scientist Inc. Sha, Tokyo, Japan. (Translation into Japanese arranged by A. Nakamura et al. Japan Uni Agency, Tokyo, Japan, 2004).
3. Stark, NJ, *Biocompatibility Testing & Management,* (1992, 1996, 1998, 2003), Clinical Device Group Inc, Chicago, IL.
4. Stark, NJ, *Clinical Trials Design,* (1996, 2000, 2002) Clinical Device Group Inc, Chicago, IL.
5. Stark, NJ, *Project Management,* (1999, 2003), Clinical Device Group Inc, Chicago, IL.
6. Stark, NJ, *Applied Regulations,* (2002, 2004) Clinical Device Group Inc, Chicago, IL.
7. Stark, NJ, *Good Monitoring Practices,* (1996, 1999, 2004) Clinical Device Group Inc, Chicago, IL.
8. Stark, NJ, *CRA Handbook* (1995, 1998, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009) Clinical Device Group Inc, Chicago, IL.
9. Stark, NJ, *Investigator's Guide to Clinical Research* (2002) Clinical Device Group Inc, Chicago, IL.
10. Stark, NJ, *Investigator Handbook: On-Site Organization and Management* (1997) Clinical Device Group Inc, Chicago, IL.
11. Stark, NJ, Editor, *US Guidances for Clinical Research* (2002, 2005, 2007, 2008, 2009), Clinical Device Group Inc, Chicago, IL.
12. Stark, NJ, Editor, *Europe Laws, Second Edition* (2002, 2005) Clinical Device Group Inc, Chicago, IL.
13. Stark, NJ, *International Clinical Trials, Third Edition* (1996, 1998) Clinical Device Group Inc, Chicago, IL.

Invited Lectures

1. Stark, NJ, "Clinical Trials: What to Do and How to Do It", MDM Rosemont Conference & Exhibition, Rosemont, IL, 24 September 2009.

2. Stark, NJ, “Medical Device Adverse Events”, Global ACRP Meeting, Seattle, WA, 22 April 2007.
3. Stark, NJ, “From Claims to Protocols”, Regional RAPS Meeting, Chicago, IL, 29 September 2005.
4. Stark, NJ, “Project Management for Medical Device Trials”, two-day training at MedicoIndustrien, Copenhagen, Denmark, 15-16 September 2005.
5. Stark, NJ, “Biocompatibility Testing & Management”, two-day training at MedicoIndustrien, Copenhagen, Denmark, 13-14 September 2005.
6. 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.
7. Stark, NJ, “European Medical Device Regulation”, three-day training at FDA/CDRH, Washington, DC. 13-15 July 2005.
8. Stark, NJ, “A Comparison of ISO 14155 and the ICH-GCPs”, Barnett/Paraxel Summit on Drug and Device Safety, 4 May 2005, Philadelphia, MD.
9. Stark, NJ, “Data Management for Medical Devices: Confusion and Controversy”, DIA Data Management Conference, 9 November 2004, Amsterdam, The Netherlands.
10. Stark, NJ, “Device Clinical Trials in the European Union”, FDA/CDRH College, 27 April 2004, Rockville, MD.
11. 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.
12. 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.
13. Stark, NJ, “Project Management for Clinical Research,” ASQ New England, 18 November 2003, Needham, MA.
14. Stark, NJ, Keynote Address: “Clinical Research Practices in the Device Industry”, ASQ New England, 18 November 03, Needham, MA.
15. 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.
16. Stark, NJ, “Clinical Databases and Part 11: The Regulated Database”, Orange County Regulatory Affairs Society, 4-5 June 2003, Irvine, CA.
17. Stark, NJ, “Clinical Databases and Part 11: A Layman’s Primer to System Documentation”, DIA Device Conference, 24-25 February 2003, San Francisco, CA.
18. 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.
19. Stark, NJ, “HIPAA Requirements and Their Effect on Clinical Research”, RAPS Clinical Trials Conference, 5-6 August 2002, Washington, DC.
20. Stark, NJ, “Predicting the Future: Clinical Research in the United States”, SoCRA, Minnesota Local Chapter, 13 June 2002, Minneapolis, MN.

21. Stark, NJ, “HIPAA—Health Insurance Portability and Accountability Act”, SoCRA, Minnesota Local Chapter, 13 June 2002, Minneapolis, MN.
22. Stark, NJ, “HIPAA—Health Insurance Portability and Accountability Act”, FDA/OCRA Educational Conference, 3-4 June 2002, Irvine, CA.
23. 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.
24. Stark, NJ, “Current US Regulatory and Ethical Issues in Clinical Research”, Regulatory Affairs Professionals Society, 20 March 2002, San Francisco, CA.
25. Stark, NJ, “Investigator Selection & Clinical Study Monitoring”, Medical Alley, 20 February 2002, St. Paul, MN.
26. Stark, NJ, “Survey of Clinical Research Practices: Medical Device Industry”, Biomedical Focus, 18 July 2001, St. Paul, MN.
27. Stark, NJ, “Current Topics in Clinical Research”, Biomedical Focus, 18 July 2001, St. Paul, MN.
28. Stark, NJ, “Device Clinical Trials in the European Union”, FDA/CDRH College, 21 June 2001, Rockville, MD.
29. Stark, NJ, “Current Topics in Clinical Research”, Medical Design & Manufacturing East, 5 June 2001, New York, NY.
30. Stark, NJ, “Clinical Trials for Medical Devices”, Regulatory Affairs Professionals Society, 2-4 October 2000, Washington, DC.
31. Stark, NJ, “Managing Subject Risk in Device Trials”, Association of Clinical Research Professionals, 15-17 May 2000, New Orleans, LA.
32. 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.
33. Stark, NJ, “Clinical Trial Site Management”, Association of Clinical Research Professionals, 21-24 April 1999, Washington, DC.
34. Stark, NJ, “Clinical Trial Site Management”, Biomedical Focus, 20-22 July 1998, Minneapolis, MN.
35. Stark, NJ, “Working with CROs”, Biomedical Focus, 20-22 July 1998, Minneapolis, MN.
36. Stark, NJ, “Health-Based Risk Assessments”, Biomedical Focus, 20-22 July 1998, Minneapolis, MN.
37. Stark, NJ, “Case Studies: Material Safety Reviews”, Medical Design & Manufacturing East97, 1-5 June 97, New York, NY.
38. Stark, NJ, “Using Foreign Clinical Data in US Submissions”, International Business Communications Conference, 15-16 August 1996, Williamsburg, VA.
39. Stark, NJ, “Managing Positive Biological Safety Result”, Biomedical Focus X, 15-17 July 1996, Minneapolis, MN.
40. Stark, NJ, “The Changing Clinical Research Industry: A Challenge for the Future”, Biomedical Focus X, 15-17 July 1996, Minneapolis, MN.
41. Stark, NJ, “Managing Positive Biological Safety Results”, Medical Design and Manufacturing West, 6-8 February 1996, Anaheim, CA.

42. Stark, NJ, "Policies of Quality and Management in Cosmetic Dermatology", International Society of Cosmetic Dermatology, 26 October 1995, Montecatini Terme, Italy.
43. Stark, NJ, "Solving Quality Problems in Biocompatibility Management", Session Chair, Medical Design and Manufacturing East, 24-26 May 1994, New York City, NJ.
44. Stark, NJ, "Identity Documentation for Materials", Medical Design and Manufacturing East, 24-26 May 1994, New York City, NJ.
45. Stark, NJ, "Materials and Surveillance Screening—Why and How", Medical Design and Manufacturing East, 25-27 May 1993, New York City, NY.
46. Stark, NJ, "Biological Safety: Design and Planning Issues", Biomedical Focus VI Conference and Exposition, 27-29 July 1992, Bloomington, MN.
47. 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.