William E. Gannon Jr., MD, MBA

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CAREER PROFILE:

MD & MBA Degree in Health Care Administration / Marketing.
Expertise in clinical development, regulatory NDA –BLA - ANDA – IND – IDE – PMA – 510K FDA submissions, strategies and approvals; commercialization, marketing and management of products and technologies for the Biotech, Medical Device, Allied Health and Pharmaceutical Industries. Diverse product experience spanning all major medical specialties, delivery methods and innovative health care practices. Extensive management of the FDA processes – all phases. Experience with European (ISO/GCP/GMP), Canadian and Japanese regulatory environments, and with IBC AHA and JCAHO regulatory affairs processes. GCP Audit and CRO assessment/evaluation experience. Current PRC, IRB, DSMB & IBC (various) committee membership(s).

PROFESSIONAL EXPERIENCE:

CSO/Medical Director **January 2005 to Present**
CAPITAL CITY TECHNICAL CONSULTING, INC., Washington, DC
www.capcitytek.com

Independent Clinical Trial/Operations & Regulatory Affairs Consultant in clinical program development and operations management. Capabilities include: Strategic (corporate) Planning, Protocol Design (Phases I – IV – Drugs, biologics and devices), Medical & Safety Monitoring, Regulatory Affairs - FDA & EU expertise (pre-IND, IND, IDE, NDA, PMA, 510k, BLA reporting and associated processes), Promotional Review Committee Membership (Medical or Regulatory), Operations Management, Team Assessment & Building, Medical Writing, CRO assessment/evaluation and GCP auditing.

Please refer to website: www.capcitytek.com – for "up to date" client & services lists

VICE PRESIDENT – CLINICAL & MEDICAL AFFAIRS **January 2002 to 2005**
CELSION Corporation, Columbia, MD

The company is an Oncology BioTech and Device firm centering its technology on the basis of heat activated delivery of treatment (device delivered) and therapeutics (thermal liposomal delivery) in the field of Oncology.

Accomplishments:

- VP – Clinical Operations – All Clinical Trials Development & operations, Data Management, Biostatistics, Medical Writing, Regulatory Affairs & FDA Submissions
- Member of Corporate Executive Team; Company liaison with FDA – all branches (CBER, CDRH, CDER)
- Restructured Clinical Department & trained existing clinical staff as to proper FDA & ICH procedures for clinical trial management. Hired staff to meet anticipated needs due to company growth. Contracted cost effective consultants to accomplish corporate target deadlines.
- Responsible for compliation and filing of PMA for BPH Device – leading to PMA Approval of the device in June 2005

- Compiled IND Filings for Breast & Prostate Cancer Liposome project(s) submission to FDA leading to clinical study starts
- Company liaison with Duke University Clinical Team & Licensing teams
- Authorship (ghost), production and demonstration of Breast Cancer Posters at 8 major clinical meetings in the USA, Europe and Asia 2002-2005
- Established SOP's and SOP process for Clinical Trial Management, Data Management, Biostatistics, Medical Writing, SAE & AE collection & processing
- Mentored and trained clinical staff; Management for F/T staff of 7 plus 8 consultants. Educated & trained R&D staff in ICH and FDA procedures where appropriate

VICE PRESIDENT – CLINICAL & MEDICAL AFFAIRS **March 2000 to January 2002**
Vaccinogen (Fomerly INTRACEL) Corporation, Frederick, MD

The Company is an integrated biopharmaceutical company focused on the development and commercialization of cancer vaccines and immunotherapeutic and diagnostic products for both cancers and infectious diseases. The company has corporate offices in Rockville, MD and manufacturing facilities in Emmen, the Netherlands.

- Responsible for design(s), strategy(s) submission(s) and execution(s) of Phase I – IV Clinical Trials, both in the US and in Europe. These efforts lead to the removal of Clinical Hold on the tumor vaccine trial programs
- Restructured and implemented Clinical Trial Plan(s) and Regulatory Strategy(s) - US & European– for both retrospective and prospective compilation(s) and submissions, for the advancement of the Autologous Tumor Vaccine Therapy for Colon Cancer and the non-specific immunotherapeutic therapy (KLH) for Bladder Cancer (CIS) into Phase III trials
- Reorganized, re-staffed and manage the Clinical Trial Management, Clinical Data Management, Biostatistics, Medical Writing, Regulatory Affairs, and Quality Assurance teams
- Clinical liaison and manager for all joint venture partnerships, contract research affiliations (both corporate usage and contractual to clients.), and business development activities
- Designed and implemented Clinical Trial Plan(s) for the reestablished Monoclonal Antibody Division
- Established Medical Advisory Board
- Other responsibilities as described in various positions below

Quintiles MTC, Inc.
Arlington, VA / Rockville, MD **August 1998 to March 2000**

A Division of Quintiles Transnational Corp., the market leader in full-service contract research, sale and marketing service to the worldwide pharmaceutical, biotechnology and medical device industries, and provides healthcare policy consulting and health information management services. Headquartered in Research Triangle Park, NC, the company has more than 30,000 employees in 45 countries.

SENIOR DIRECTOR, U.S. CLINICAL OPERATIONS- Medical Device Division **February 1999 to March 2000**

- Responsible for the clinical operations team for the Medical Device Unit, restructured, reorganized and managed in addition to pharma projects. Increased utilization from 38% to 62% is the first two months. Increased division revenues by 40% and RFPs by 30% over the prior year.
- Responsible for the management, oversight, training and growth of a staff of 40, including PMs, Sr. CRAs, CRAs, RAs and PAs.
- Responsibilities (as listed below) of Medical Affairs Physician / Director Medical Writing were included in this position as well

DIRECTOR - MEDICAL AFFAIRS **August 1998 to February 1999**

- Designed, implemented and managed Protocols & Clinical Trials – Phases I-IV in areas of Respiratory, Infectious Disease, Anti-Infectives, Dermatology, Oncology, CNS, Psychology, Cardiovascular, GU, GI, General Medicine, Medical Devices, Diagnostic agents, Allergy, and Biotech compounds for NDA, ANDA, IND, IDE and PMA submissions
- Managed Medical Writing Division for Therapeutic Group 3. Increased utilization by 14% to 80%. Increased division RFPs by 65%.
- Active in the procurement of new business, serving as clinical/technical (regulatory) support to the Business Development Division
- Member of Team(s) responsible for rewriting/structuring Global Corporate SOPs and SOPs for Medical Affairs & Medical Writing – North American Divisions

MEDICAL DIRECTOR **February 1997 to May 1998**
PPD Development, Inc. (formerly PPD/Pharmaco, Inc.), Wilmington, NC

A Division of PPDI, PPD Pharmaco is a full-service, international, Contract Research Organization servicing the Pharmaceutical, Biotech and Medical Device Industries in the development, execution and conduct of clinical research (Phases I – IV and Post Market) for NDA – ANDA – IND – IDE – PMA submissions and approvals by the FDA and appropriate International Agencies for patient use. Currently, there are 41 offices Worldwide, 3 main Clinical Divisions in US (Wilmington, NC, Research Triangle Park, N.C. and Austin, TX) and $185 million in annual revenues. It is currently ranked as the third largest CRO. Reported to CEO and Senior VP of Medical Affairs/Chief Safety Officer, in matrix, and served as the 2nd in list of 5 Medical Safety Officers for the North American Division.

- Designed, implemented and managed Protocols and Clinical Trials – Phases I-IV in the areas of Respiratory, Oncology, CNS, Psychology, Cardiovascular, GU, GI, General Medicine, Medical Devices, Diagnostic Agents, Allergy, and Biotech compounds for NDA, ANDA & PMA FDA submissions
- Medical management of up to 12 protocols/trials at any given time
- Member of Team(s) responsible for rewriting/structuring Global Corporate SOPs; North American QC/QA policies/procedures, and SOPs for Medical Affairs and Medical Writing – NDA submission procedures in the North American Divisions
- Managed the Medical Writing Division for North America – restructured and more than tripled staff in 6 months and increased utilization by 34% to 85%. Doubled division sales. Group produced an average of 75 reports for NDA – ANDA – IND – PMA – IDE submissions, 100 protocols, and 30 manuscripts annually
- Active in the procurement of new business, served as clinical/technical (regulatory) support to the Business Development Division Worldwide
- Created and implemented business development plan for the establishment in the Medical Device Division of the organization. Provided the same expertise that was conducted on the pharma side of the field
- Established and staffed Medical Device Division, from the onset – 6 full development projects at a PM of 61% within the first six months of operation

DIRECTOR, MEDICAL AFFAIRS & CLINICAL DEVELOPMENT **April 1994 to October 1996**
Nastech Pharmaceutical Co., Inc., Hauppauge, NY

R&D Company involved in the development of Rx and OTC compounds for the pharmaceutical industry as well as an internal product portfolio of intranasal product lines. Involvement in patent and development licensures. Three operating divisions and $8-10 million in annual revenues

- Designed and implemented new product evaluation process for use in reviewing patents and formulations held by the company to enter its R&D pipeline or to be licensed out. Completed 55 compounds through process within the first year

- Evaluated company's existing and proposed product line(s) for applicability and marketability in the pharmaceutical industry and healthcare facility environment
- Created new product evaluation process to review outside products for possible acquisition by the company. Completed 21 potentials through process within the first year. Designed and implemented a company-wide budgeting process. Updated and expanded in-house computerized library
- Served as direct liaison with the FDA and completed submissions for the 6 NDAs, 3 INDs and inspections
- Evaluated, contracted and managed the company's CRO use in five pre-clinical and clinical studies, Phase I – IV, (vitamin, sleep aid, narcotic analgesic, antihistamine and motion sickness categories)
- Developed the marketing department and all marketing plans for current products, corporate requirement and new product launches. Assembled MD review board for scientific input

DIRECTOR, CLINICAL DEVELOPMENT & MEDICAL AFFAIRS **March 1991 to March 1994**
ISG Technologies, Inc., Toronto, Canada

Company designed, manufactureed, marketed and serviced computer-based visual data processing systems for the medical and surgical imaging industry to assist in providing non-invasive, diagnostic alternatives to exploratory surgery. 100+ employees and billings of approximately $16 million annually.

- Initiated, designed and implemented clinical development and regulatory affairs programs. Expanded the scope and depth of corporate marketing program
- Established clinical research site with leading physicians/researchers in surgery, radiology and dental to support the company's product lines
- Managed clinical site program, Phases I and II, for neurosurgical product, consisting of 15 sites worldwide, involving over 45 MD/researchers and with 15-20 projects ongoing
- Involved in all phases of new product development including neurosurgical localizer instrument, "Viewing Wand" neurosurgical localizing/navigational product and physicians' image review station
- Directed company compliance with national and international medical regulatory agencies including FDA-510Ks, PMAs, GMP, ISO 9000 and MOHs (Canada and Japan)
- Provided training and education in sales, marketing and applications for training staff
- Supported national and international sales efforts, trade shows, demonstrations and corporate presentations

VICE-PRESIDENT, MEDICAL AFFAIRS **May 1990 to January 1991**
The AVMD Group (Audio Visual Medical Marketing, Inc.), New York, NY

Full-service, international pharmaceutical, healthcare and medical communications company consisting of 4 divisions, 75 + employees and billings of approximately $30 million annually. The company conceptualizes, develops and produces a wide variety of research, educational and promotional programs for the pharmaceutical/healthcare industry on the national and international level. Specific product area expertise includes biotech, cardiovascular, GI and Alzheimer's disease.

- Directed protocol development and a staff of 1 MD and 6 Pharm.Ds for NDA submissions, Phase IV and V clinical studies
- Involved in all phases of strategic and marketing plan development, product positioning and creative project development. Managed development and presentation of all new business proposals
- Appointed company liaison to the medical / scientific and allied health leaders and communities
- Additional responsibilities as listed in Medical Director position from previous employment

MEDICAL DIRECTOR **April 1989 to May 1990**
Klemtner Advertising, Inc., New York, NY (Division of Saatchi & Saatchi Advertising Worldwide)

Pharmaceutical, healthcare and medical marketing, advertising and program development firm consisting of 120+ employees and $115 million in annual billings. Serves clients on the national and international level. Specific product experience in biotech, antibiotics, antihypertensives, estrogen replacement, anti-inflammatories, Rx to OTC conversions, and OTC medical products.

- Developed an extensive network of physicians and allied health professionals on behalf of the agency and its clients for product advocacy, consultation, focus panels, product evaluations and marketing/promotion
- Participated in the development of strategic, marketing and creative/promotional plans for all agency clients
- Reviewed materials, plans, protocols, scientific-promotional-educational projects for medical/technical accuracy and regulatory compliance with FDA, JCAHO, AHA and other national organizations
- Reviewed and critiqued clinical papers and studies. Developed protocols – Phases I-IV

NOTE: Major clients and products included RPR (Orudis, Selecor); Bristol-Myers/Squibb (Monopril, Pravastatin); Wyeth/Ayerst (Premarin); Boehringer/Ingleheim (Dulcolax); and Upjohn (Rogaine)

EDUCATION:

MBA/ Concentration in Health Services Administration - February 1988
The George Washington University, Washington, DC

Doctor of Medicine - January 1985
Ross University, School of Medicine, New York, NY; Roseau Dominica

Post Graduate/ Residency Training, Case Western Reserve System & GWU
Family Practice, **1985 - 1987**
Robinson Memorial Hospital, Ravenna, Ohio
Trumbull Memorial Hospital, Warren, Ohio

Bachelor of Arts - May 1981
The Catholic University of America, Washington, DC

IRB, DSMB, IBC, CLINICAL ADVISORY BOARDS, PROFESSIONAL ORGANIZATIONS & AFFILIATIONS:

NIAID/NIH/DHHS – HIV-AIDS Research Review Committee	2013-Present
OTSUKA Pharmaceuticals America, Inc. (OAPI) – PRC (DDMAC Clearance)	2007-Present
DMID/NIAID/NIH - DSMB – Vaccine Committee	2010-Present
BCAN (Bladder Cancer Advocacy Network) – Advisory Board Consultant	2007-Present
AREAS Corporation - IBC	2006-Present
Intercell, Inc.(Kendle - CRO) - IRB	2010-2011
TOTAL IRB	2009-10
AVI Inc. - DSMB	2008-09
Great Lakes IRB	2007-10
Aspen Publishing, Inc.; Frederick, MD – Editorial Advisory Board Member	2001-03
EER Medical Systems; Chantilly, VA– Clinical Consultant	2001-03
SMA Medical Corporation; Irvine, CA– Clinical Advisory Board Member	2000-02
The Health Exchange, Inc.; Stamford, CT– Clinical Advisory Board Member	2000-02

BOARD of DIRECTOR AFFILIATIONS

APTHERA, Inc. – Member – Board of Directors 2005-2011
CYTIMMUNE SCIENCES, Inc. - Consultant to Board of Directors 2005- Present
CUREMARK, LLC – Advisor to Board of Directors 2008 – Present
PROTALEX, Inc. – Consultant to Board of Directors 2009 to Present

PROFESSIONAL ORGANIZATIONS & AFFILIATIONS

AdvaMed (Advance Medical technology Association) – Current Member
Drug Information Association – Current Member
Regulatory Affairs Professional Society (RAPS) – Current Member
ACRP/American Academy of Pharmaceutical Physicians & Investigators – Current Member
Vice President, Public Relations Committee, Membership Committee – 1994 – 1997
American Association of Pharmaceutical Scientists – '94-97
Associates of Clinical Pharmacology – '95 - 99
American College of Healthcare Executives – '88 - 91

PUBLICATIONS:

PTRX-100 in Combination with Methotrexate in Patients with Active Rheumatoid Arthritis: A Phase 1b Ramdomized, Double-Blind, Placebo-Controlled, Multiple Dose, Safety Study: Bernton, E; Gannon, W.E; Krantz, E., American Journal of Rheumatology. Q3 – 2013

The Value of EDC in Early Stage Clinical Trials. Gannon, W.E., Life Science Leader . Q1 - 2012.

Phase I & Pharmacokinetic Studies of CYT-6091, a Novel PEGlyated Colloidal Gold-rh TNF Nanomedicine. Tamarkin,L.; Gannon, W.E. et al., Clinical Cancer Research, January 2011.

Expanded Market Opportunities Using Nasal Drug Delivery: A Case Study. Gannon, W.E., AAPS Journal, December 1995.

Nasal Vitamin B12: Intranasal Versus Intramuscular Serum. Vitamin B12 Profile in the Treatment of Vitamin B12 Deficiency Anemia. Romeo, V.D.; Sileno, A.P.; Gannon, W.E., AAPS Journal, October 1994.

The Viewing Wand – A New System for 3-Dimensional CT – Correlated Interoperative Localization. Leggett, B.L.; Greenberg, M.M.; Gannon, W.E.; Dekel, D.; Gabe, C.J., Current Surgery, December 1991.

PRESENTATIONS:

Co-Author - A Phase 1 Randomized, Double-blind, Placboe-controlled Multiple-dose Study of Intravenous Staphylococcal Protein A in Patients with Active Rheumatoid Arthritis on Methotrexate: Pharmacokinetics, Safety, and Tolerability – American College of Rheumatolgy Annual Meeting – Washington, DC, November 2012

Meeting Leader – BCAN (Bladder Cancer Advocacy Network) Annual Meeting – Stowe, VT, August 2012

Speaker - The Value of EDC in Early Stage Clinical Trials. Gannon, W.E., AAPS Annual Mtg Presentation. October 2011

Meeting Leader – BCAN (Bladder Cancer Advocacy Network) Annual Meeting – SanDiego, CA, August 2011

Meeting Leader – BCAN (Bladder Cancer Advocacy Network) Annual Meeting – Traverse City, MI, August 2010

Medical Leader – Investigator's Meeting – Phase I Trial in Vaccine Therapy Treatment of Rheumatoid Arthritis – Protalex, Inc.- George, South Africa – May 2010

Meeting Leader – BCAN (Bladder Cancer Advocacy Network) Annual Meeting – Jackson Hole, WY, August 2009

Medical Leader – Investigator's Meeting – Phase III Clinical Trial for Autism - Curemark, Inc, Rye, NY, November 2008

Speaker – "The Role of Industry in Funding Clinical Trials in/for Academic Cooperative Groups" – Children's Cause for Childhood Cancer Advocacy Annual Meeting – New York City, NY – October 2008

Medical Leader – Investigator's Meeting – Phase II Clinical Trials in Nanotechnology in Oncology – CytImmune Sciences, Inc., June 2008

Speaker – "The Role of Industry in Funding Clinical Trials in/for Academic Cooperative Groups" – BCAN (Bladder Cancer Advocacy Network) Annual Meeting - Washington, DC, September 2007

Panelist - Oncology Clinical Trial Summit – Arlington, VA, September 2007

Emerging Novel Technologies in Bladder Cancer: 2nd Annual JHU Bladder Cancer Think Tank, Cape Cod, MA, August 2007

Emerging Novel Technologies in Cancer Therapies: Partnerships with CRO's, Orlando, FL, March 2007

Focused Microwave Phased Array for Targeted Treatment of Primary Breast Tumors: ESHO 2003, Munich, Germany, June 2003

Thermodynamic Therapy for the Treatment of Cancer: ESHO 2003, Munich, Germany, June 2003

Phase II Clinical Studies of FMPA for Primary Breast Cancer – Progress Report: ESHO 2003, Munich, Germany, June 2003

Web Based Clinical Trials: Where are We Today and Where Are We Headed
Web Based Clinical Trials Conference: New Orleans, LA, March 2001, Boston, MA, October 2001

Autologous Vaccine Therapy – Panel Discussion
ASCO Annual Meeting, New Orleans, LA, April 2000

Third Annual Medical Device Industry Conference: Legislative Update '98
San Francisco, CA, March 1998

Intranasal Drug Delivery: Commercial Advantages
AAPS Conference, Miami, FL, November 1995

Innovative Drug Development '95: Company Overviews
Technologies and Opportunities Communitech Conference, New York, NY, May 1995

CAS in Neurosurgery – Overview and Clinical Applications
Stereo tactic Conference UCLA, Los Angeles, CA, August 1992

CAS Systems and Its Applications to FESS
First International Congress for Advance FESS, Vienna, Austria, July 1992

Minimally Invasive Surgery – CAS in Neurosurgery
Biomedical Business Institute, San Diego, CA, May 1992

3-D Imagery: A Role in Radiology Today
Radiology Society of North America, Chicago, IL, December 1991

Impact of Computer Technologies on the Department of Surgery
Northeast Hospital Conference, Baltimore, MD, April 1989

POSTERS:

Results of a Phase I Clinical Trial of CYT-6091: A PEGylated Colloidal Gold-TNF Nanomedicine: ASCO Annual Mtg. June 2010

Preliminary Results of a Phase I Clinical Trial of CYT-6091: A PEGylated Colloidal Gold-TNF Nanomedicine: ASCO Annual Mtg. June 2007

Phase II Clinical Studies with FMPA for Primary Breast Cancer – Progress Update: ASBS Annual Mtg., Miami, FL, and February 2003

New Drug Delivery Approach for the Treatment of Prostate Cancer: CaP Cure Annual Mtg.: Washington, DC. September, 2002

Ongoing Phase II Clinical Studies of Focused Microwave Phased Array (FMPA) Thermotherapy for Primary Breast Cancer: American Society of Breast Surgeons (ASBS) Annual Conference: Miami, FL, March, 2002