EXPERIENCE

DRUG MANAGEMENT-BUSINESS EXPERIENCE

- Burroughs Wellcome
- Orphan Medical (Co-Founder and President)
- Board of Directors (6 companies)
- Advisory Boards (7 companies)

DRUG DISCOVERY RESEARCH

- Pfizer
- Philips-Duphar
- Sterling Winthrop

TRADE ASSOCIATION

- PhRMA—Senior Vice President

REGULATORY AFFAIRS

- International Conference on Harmonization (ICH) — Steering Committee & Co-Chair, Global Cooperation Group
- Broad Experience with Many Regulatory Agencies

AUTHORSHIP

- 15 Reference textbooks, including "Guide to Clinical Trials"
- 140+ Articles; 14 Book chapters

TEACHING

- Over 40 one- to three-day courses in 11 countries

ACADEMIC APPOINTMENTS

- Clinical or Adjunct Professor:
  University of North Carolina
  Duke University
  University of Minnesota

CLINICAL PRACTICE

- Internal Medicine
- Cardiology Clinic

(Curriculum Vitae available at **www.bertspilker.com**)

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— **Tachi Yamada, M.D.**
Chairman, Research & Development
GlaxoSmithKline

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President, Pharmaceutical Research Institute and Chief Scientific Officer
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- Pharmaceutical Companies
- Biotechnology Companies
- Contract Research Groups
- Trade Associations
- Consulting Organizations
- Regulatory Firms
- Investment Banks & Firms
- Think Tanks
- Law Firms

KEY SERVICES

REGULATORY & POLITICAL AFFAIRS

- Advise companies on clinical or regulatory strategies
- Evaluate regulatory submissions
- Guide foreign companies entering the US market
- Advise companies on political affairs and health policies

DRUG DEVELOPMENT/CLINICAL TRIALS/LICENSING

- Strategize on drug development approaches to achieve early approval
- Create or evaluate strategies for optimizing clinical protocol contents and design
- Prepare or evaluate reports or other materials
- Conduct licensing due diligence

SCIENTIFIC MANAGEMENT FOR EARLY STAGE CORPORATIONS

- Counsel on scientific management issues
- Assess organizational structure and strategies
- Review business plans
- Conduct legislative analyses

TRAINING IN CLINICAL, REGULATORY AND PROJECT MANAGEMENT

- Conduct in-house courses
- Mentor senior R&D staff

PRACTICAL SERVICES

- Facilitate, moderate or attend meetings at your organization
- Attend external meetings on your behalf
- Speak on behalf of your organization
- Write or edit white papers

LEGAL SUPPORT SERVICES

- Develop strategies and analyze medical documents
- Serve as an expert witness

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