官员，器械注册司,国家食品药品监督管理局
Officer，**Department of Medical Device Registration,** CFDA

钱虹，首席评审员、上海市食品药品监督管理局认证审评中心
Hong Qian, Minister, Medical Device Registration Department of Shanghai Food and Drug Administration Certification and Evaluation Center
上海市食品药品监督管理局认证审评中心，主要从事医疗器械产品注册技术审评工作

李卫，教授、博导，国家心血管病中心医学研究统计中心
Wei Li, Professor,Ph.D. supervisor, Medical Research & Biometrics Center National Center for Cardiovascular Disease, CHINA
李卫，法国里昂一大生物统计博士、香港中文大学公共卫生学院流行病与生物统计博士后。现任国家心血管病中心医学统计部主任,国家食品药品监督管理局(SFDA)临床试验审评专家，国家科委及北京市科委审评专家。主要从事药物和医疗器械临床试验研究设计及统计分析方法学研究。并为政府、企业及大专院校提供临床试验统计咨询服务。作为课题负责人，目前承担着数十项国内外多中心临床试验研究课题，还作为协作者，参加多项国家重大课题。在国内外 SCI 收录杂志上发表第一作者署名的英文文章数十篇，参与撰写论著 6 部。
Prof. Li Wei, Postdoctoral Fellow in Biostatistics. The Chinese University of Hong Kong, Hong Kong.
Now, she is the director of the Division of Biometrics, National Center for Cardiovascular Diseases. Prof. Li Wei has many experiences in study design, data management and statistical analyses for drug/medical device clinical trials, and she is the senior external advisor of the State Food and Drug Administration (SFDA). As first author or corresponding author, she has published many SCI English papers.

姜爱国，亚太及新兴市场质量总监，施乐辉公司
Alex Jiang, Quality Director of APAC & Emerging Markets, Smith & Nephew
姜爱国，施乐辉公司亚太及新兴市场质量总监。全面负责公司在该区域的产品研发，产品制造，产品流通和销售过程中的质量管理。鉴于其深厚的计算机模式识别的专业背景，对于全球医疗法规框架下，医疗产品全球身份证制度（UDI）的实施有独到的理解，参与了中国医疗器械产品标识法规和标准的促进和发展工作。在标签转换，建立产品注册信息管理和库存管理计算机系统具有系统的经验。应对国际上 UDI 法规实施要求，他创建的产品注册的标准流程关联 UDI 实施要求运用于各类标签转换系统，已经获得国际 ISO13485 质量管理体系认证。
Alex Jiang， Quality Director of APAC & Emerging Markets in Smith & Nephew. He has the overall responsibility for Quality Management in Research & Development， Manufacturing， and distribution & sales in this region. He has distinctive understanding of global Unique Device Identification (UDI) system under the global regulatory framework for medical devices， with his particular expertise of

computer pattern recognition. He actively participates in promoting and developing the regulations and standards for the identification of medical devices. He has the systematic experience for labeling conversion， product registration information management and inventory management software systems. To meet the requirements of global UDI regulations， he built the integrated system， associating the standard process for product registration and the requirements of UDI， to control all kinds of labeling conversions， which has been certified under ISO13485 quality management system certification.

蔡天智，副秘书长、主任，中国医药保健品进出口商会、医疗器械部

Tianzhi Cai, Deputy Secretary – General, minister, CHINA CHAMBER OF COMMERCE OF MEDICINES & HEALTH PRODUCTS IMPORTERS & EXPORTERS

现任中国医药保健品进出口商会副秘书长兼医疗器械部主任，商务部援外项目评审专家，高级经济师，上海交大安泰经济与管理学院和清华大学继续教育学院医疗装备事业高级管理人员 MBA 核心课程导师，兼任《世界医疗器械》杂志编委及《现代仪器与医疗》杂志高级编委。目前从事医药、医疗产品国际贸易促进、分析与咨询，医药经济运行预测及援外项目管理等方面的行业工作。

张浩基，总经理，中国国际医药卫生公司器械事业部

Haoji Zhang, General Manger , China Sinopharm International Corperation Medical Device Dept.

Ilya Yakushev，医疗器械注册总监，Elmas Ltd

Ilya Yakushev，Registered Director of Medical Devices，Elmas Ltd

KEY COMPETENCE : Over 5 years of experience in Regulatory consulting and product certification industry； Solid understanding of Market Access strategy for Medical products in Russia & CIS；Medical and non-medical products certification and approval in Russia and Eurasian Customs Union；Familiarity with government legislations and regulations affecting medical industry in Russia .

WORK EXPERIENCE: ELMAS LTD – Head of Asian Division, Department of Medical Device Registration (current job)

Market Access and Regulatory consulting (Russia and CIS countries); Project management (Active MD, Dental, IVD);Regulatory training and seminar (MD market access);EAC, Telecom, GOST-R approval (Active medical products);

王英，公司监事、市场部总监，稳健医疗用品股份有限公司

Ying Wang, Marketing Director , Winner Medical Co., Ltd
毕业于西南交通大学，12 年的医用敷料行业从业经验，从事医用敷料外贸出口 8 年，对医用敷料国际市场有深入了解，“医用敷料行业发展竞争力前瞻”。

赵辉，总经理，北京驼人国际贸易有限公司
Hui Zhao, General manager, Beijing Tuoren International Trade Co.,Ltd
毕业于西安财经大学经济学专业。现任驼人集团北京驼人国际贸易有限公司总经理职务。主要负责集团海外市场的规划开发；目标国际市场的渠道开发建设；海外分公司的建设管理；海外高技术产品合作引进等工作。曾工作于中国医疗器械行业协会国际合作部。主要负责国际行业组织对接；帮助国内企业进入海外市场；帮助国外公司寻找国内技术引进方等相关工作。
Zhao Hui is the general manager of Beijing Tuoren International Trade Co.,Ltd which is one of a subordinate company of Tuoren group . He graduated from Xi'an University of Finance and Economics in 2003. He worked in the International cooperation department of China association for medical devices industry(CAMDI) from 2003 to 2006,the mainly work included coordinating with international trade organization ,Helping domestic enterprises enter the overseas markets; Helping foreign companies to find technology importer in China,etc. Now, as a general manager of Beijing Tuoren International Trade Co.,Ltd, his mainly work include making the development plan of international market ; Establishing and developing sales channels for target markets; Establishing and managing the oversea company and branch ;Introducing the high-tech production cooperation from overseas,etc.

萨盾，驻华办公室助理主任，美国食品药品管理局
William M. Sutton,FDA Assistant Country Director, China
萨盾是在美国食品药品管理局（USFDA）国际项目办公室下属的 FDA 驻华办公室助理主任，他负责医疗器械的国际项目和政策分析。在被任命为 FDA 驻华办公室助理主任之前，萨盾先生是医疗器械和放射健康中心（CDRH）的行业与消费者教育处（DICE）副处长。他主要负责该处在医疗器械上市前喝上市后相关法规教育工作的战略发展。萨盾先生 1983 年起开始在 FDA 工作，曾在医疗器械评审办公室（ODE）和交流教育办公室（OCE）工作。在 FDA 工作期间，曾在 ODE 担任行政评审员，在 OCE 的企业和国际协助项目中担任消费者安全官主管。在这两项工作中，他负责国内和国际合规事务，并担任 FDA 第三方认可委员会（TPRB）主席，管理 510(k)评审的认可人员（AP）和现场检查的 AP。在过去的 21 年中，他参与了多国大量医疗器械相关联邦法规政策的培训。萨盾先生获得马里兰大学大学学院分校的科学管理学士学位。
William (Bill) Sutton is an Assistant Country Director in the Office of International Programs (OIP) at the United States Food and Drug Administration (FDA) China Office where he serves as the International Program and Policy Analyst (IPPA) for medical devices. Before being named Assistant Country Director of the FDA China Office, Mr. Sutton was the Deputy Director of the Division of Industry and Consumer Education (DICE) at FDA’s Center for Devices and Radiological Health (CDRH) where he led the Division in the strategic development of regulatory education on medical device topics spanning premarket and postmarket policy. Mr. Sutton began his career at FDA in 1983, and has held positions in CDRH, the Office of Device Evaluation (ODE), and the Office of Communication and Education (OCE). During his tenure at the FDA he served as an administrative reviewer at ODE and as a Supervisory Consumer Safety

Officer at the mandated industry and international assistance program in OCE. In both roles he worked on domestic and international compliance issues, and served as Chairman of FDA's Third Party Recognition Board (TPRB), which administered both the Accredited Persons (AP) for 510(k) review and AP for Inspection programs. For over 21 years he has educated the worldwide medical device community about Federal medical device regulations and policies. Mr. Sutton received a Bachelor of Science in Management Studies from the University of Maryland University College.

陳維斌, 东亚区总监，德凯集团

Mr. Roger Chen ,Market & Sales Director, Healthcare, East Asia, DEKRA

Roger Chen has more than 15 years of experience in TIC industry. And working in Medical device field for more than 14 years for active device testing, regulation such as FDA 510(K), CE MDD, Japan PAL, CFDA registration and ASEAN registration…etc. for GC and ASIA markets with experience of progress for both of regulation and technology for medical device. In addition, working in multi-national company allowed me to experience different culture what can support ASIA manufacturers have full understand of the core of regulation from western society.

柳美荣，医疗研发经理，NAMSA

Minna Liu ,Medical Research Manager, NAMSA

柳美荣女士在医疗器械行业有超过十五年的从业经验，其中包括医疗器械的研发、生产、注册、质量、临床试验等。熟悉中国和欧盟的相关法规，在任职的国内外医疗器械公司，先后成功完成了数百项进口及国产医疗器械的 CFDA 注册工作，以及部分 CE 认证申报以及质量管理、上市后监管工作。近年来尤其加入 NAMSA 后，Minna 更是致力于临床评价工作的开展和团队的建设，目前中国临床评价报告（CER）的申报成功率为 100%。除了丰富的法规专业知识外，Minna 还是 ISO 组织－全国外科植入物和矫形器械标准化技术委员会第二分技委的委员，积极参与相关标准、法规的起草工作。

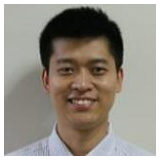
Minna Liu has more than 15 years of experiences in within the China medical device industry. She has successfully completed hundreds of imported and local medical device registrations while working at Cook, Bard and Grikin. In addition to her extensive regulatory expertise, Minna is a certified delegate for the ISO organization - SAC/TC110/SAC and is an expert on medical device standards. Ms. Liu is also an experienced Quality Assurance expert, with particular expertise on ISO 13485. Prior to her RA/QA career, Ms. Liu used her engineering background for research and development of medical devices, resulting in 10 Chinese patents and 8 published journal articles. Ms. Liu received her master degree in material science and engineering from Beijing University of Aeronautics and Astronautics.

蔡燕，总监，NAMSA 中国实验室

Yan Cai, director ,NAMSA China lab director

蔡燕博士，目前是 NAMSA 中国实验室运营总监。蔡博士在中国药科大学获得生物工程制药专业学士学位，随后在中科院上海药物研 究所药理毒理专业取得博士学位。蔡燕博士具有超过十年的 GLP 动 物实验室建设及管理经验。并负责了多项药物安全性评价方案的制 定、动物实验的手术实施、监督和实验报告的撰写。蔡博士同时具 有丰富的遗传毒理学研究经验。

Dr. Yan Cai is Director of China Lab Operation. Yan is responsible for establishing and developing NAMSA China Lab. Yan most recently worked in Medicilon Preclinical Research (Shanghai), LLC as Director of Lab Sciences. She managed a team of 60 staff at Medicilon, where she planned, directed and coordinated lab operation and hired, trained, and supervised lab team. Yan also held several other technical leadership positions in Medicilon including Study Director, Director of Toxicology, Director of Pharmacokinetics and, and Director Quotation/Pricing. Yan has been involved in scientific and regulatory consulting, client management, and business development in pharmaceutical research. Yan is a Certified Toxicologist of Chinese Society of Toxicology (C.T.C.S.T), received a variety of GLP trainings. Yan obtained her Ph.D. in Toxicology from Shanghai Institute of Material Medica, Chinese Academy of Sciences and BS in Biochemistry from China Pharmaceutical University Nanjing China.



李朝辉,亚太区市场销售总监，NAMSA

Zhaohui Li, sales director ,NAMSA APAC

李朝辉博士目前是 NAMSA 亚太区市场销售总监，负责 NAMSA 全球各项临床前测试，临床测试与法规咨询业务在亚太区市场的业务拓展和销售。李博士多次在国际国内会议上做演讲报告，多次组织了国内外医疗器械测试与法规峰会，也多次为国内外医疗器械监管机构制定并参与了医疗器械测试的培训课程。李博士之前在 TUV SUD 集团新加坡实验室作为生物相容性测试 GLP 项目负责人，执行了超过 150 个测试项目的方案制定与执行。TUV SUD 之前李博士在新加坡国立癌症中心博士后的工作中负责一项肺癌临床研究项目。李博士 2007 年于新加坡国立大学医学院取得生物神经学专业的博士学位。2000 年本科毕业于吉林大学生命科学院生物制药专业。

Dr. Zhaohui Li is Director of APAC Sales, NAMSA China. Zhaohui most recently worked in TUV SUD Singapore lab as a GLP Study Director. He managed more than 150 GLP safety and efficacy studies, including protocol development, study execution, and final report. Zhaohui had technical expertise in ELISA, bone and muscle implant, intradermal injection, IV IP injection and many other hands-on lab experiences. Zhaohui was also involved in market development, training, speaking, and sales team development for TUV SUD China testing business effort. Before TUV SUD, Zhaohui worked in National Cancer Center Singapore as a research fellow, where he managed a lung cancer clinical study; worked in National University of Singapore as a research officer studying on neurodegenerative disease. Zhaohui obtained his Ph.D. in neuroscience from National University of Singapore and BS in Biochemical Pharmaceutics from Jilin University, China.

华子恺，主任，骨科植入物与生物医学制造实验室

Zikai Hua,director,Orthopedic implants and biomedical manufacturing laboratory

华子恺博士是上海大学智能基础件研究中心主任，上海大学骨科植入物与生物医学工程实验室（Orthotek Lab，ISO17025 certified）主任，上海市徐汇中心医院副院长（挂职），英国帝国理工大学 JointsInSilico 研究中心客座教授，美国 Accutek Testing Laboratory 客座研究员。现任全国外科植入物与矫形外科器械标准化委员会委员（SAC/TC 110/SC1），中国生物材料先进

制造分会委员，中国机械工程学会摩擦学分会青工委委员，上海市康复医学会神经康复专业委员会常委、康复工程专委会委员等。长期与国内医院开展医工结合工作，研究转化医学中的工程问题，在康复工程、外科植入物等医疗器械方面进行合作。曾获上海市科学技术进步奖（三等奖）、上海市优秀博士论文、上海市市民创造发明成果奖。近三年，在相关领域国际一流期刊及会议发表论文 60 余篇、授权/申请发明专利 10 项、参编专著 3 本、主持完成国家及企业科技攻关项目 30 余项。

虞则立，RAC，Global

Zeli Yu , RAC , Global

虞则立先生毕业于上海交通大学附属医学院，在其 24 年的医疗行业从业经历中， 先后服务于惠普医疗，TUV 产品服务公司，英标 BSi 产品服务公司并且分别担任动脉血气 （POCT）床边检测专家，公告机构审核员，FDA510(K)第三方评审员，中国健康医疗部经理等职位，客户包括 BD 诊断，强生医疗等，虞先生于 2016 年获得全球医疗器械法规的职业资格 RAPS 的（RAC，Global），目前虞先生作为独立高级法规咨询师，同时向本土和跨国医疗器械制造商提供健康领域法规符合性咨询服务。同时，作为 FDA 的 510(K)，21 CFR820 和 ISO14971 证书获得者，凭借其 1000 人天以上的欧美法规 MDD 和 IVDD 审核经验，63 次 FDA 21CFR820 的现场 QSIT 检查经历和 5 个完整的 510(K)成功申请案列， 虞则立分别于 2011 年和 2012 年成为 RAPS 在华美国法规的讲师和强生医疗，雅培诊断，和捷迈全球供应商审核项目的主任审核员。

从 2012 至 2014 年间，虞则立拓展了为捷迈，施乐辉，强生，雅培等全球采购的跨国公司的亚洲供应商审核业务，致力于供应链的 ISO 13485，21CFR820cGMP 和 21CFR58GLP 的符合性评估检查。同时虞则立领导了史赛克大中国贸易公司的 ISO13485 的符合性咨询工作，这是在医疗器械贸易公司业务中第一家包括大陆，香港，台湾两岸三地的 ISO 多地点认证，它很大程度地支持了后续中国 GSP 法规的符合性。

虞则立先生凭借其优秀的语言沟通能力和多年的医疗器械法规符合性的经验，成功的协助日本最大的医疗器械公司解除美国进口限制和 FDA 的警告信。在 2015 年虞则立更成功地协助全球最大的医疗器械制造商美敦力使其在华工厂 VAI 完成了第一次 FDA 的 QSIT 工厂检查。

至 2017 年，虞则立先生已经完成了 63 例 FDA 工厂检查的现场陪同工作，其中 49 次以零缺陷协助 FDA 完成了 QSIT 的 Level II 检查，其中包括美敦力，泰尔茂，艾康生物科技，九安电子，东软飞利浦，BD 诊断，施乐辉，强生医疗器械。

同时，随着中国 CFDA 的海外检查的开展，，从 2015 年底开始虞则立越来越多的开展和进行工厂的检查和准备工作，目前已积累四个项目的经验，虞先生的经验包括但不局限于：

- 让制造商了解检查组的组成，与中国的同事沟通 QMS 技能，使其了解 IVD 的 Annex IV，MDD 的 Annex II 以及 QSR 820 的基本知识
- 澄清如何使用 CFDA 法规 64 和 218 现场检查表
- 制造商的作战室和前室设置，有别于美国 FDA 现场检查时候的设置
- 支持项目组利用 CFDA 法规进行差异化分析
- 模拟审计的必要性
- 在工厂团队中选择潜在的翻译候选人，为现场检查做准备
- 翻译者的翻译技能发展
- 根据 CFDA 的检查主文档清单来准备相应的文件记录

Graduated from the Medical College Affiliated to Shanghai Jiao Tong University, in his 24 years medical device career, Mr. Scott Yu worked on different positions of Point of Care （POCT）Specialist, Notified Body Auditor and China Healthcare Manager, FDA 3rd Party Reviewer for HP Medical (I-STAT), TUV Product Service, BSi Product Service respectively and his customer cover BD diagnostic, Johnson & Johnson etc. Mr. also got the (RAC global) credentials at RAPS in 2016. At present, Mr. Yu, as an

independent senior regulatory consultant, he provides Healthcare Regulatory Compliance Services to local and global medical device company. As the owner of the FDA 510(K), 21 CFR 820 and ISO 14971 certificate, Mr. Yu became to be the US Regulation Tutor for RAPS in China in 2011 and the Johnson & Jonson Ethicon, Abbott Diagnostic, Zimmer Biologic Global Supplier Lead Auditor in 2012 based on his more than 1000 man days EU & US regulatory compliance audits (MDD & IVDD), 63 times FDA 21 CFR 820 on site QSIT experience and 5 successful 510(K) submissions.

From 2012 to 2014, Mr. Yu further develop the 2nd party audit business scope for Zimmer, Smith Nephew, Johnson & Johnson, Abbott Diagnostic etc. global company in the field of ISO 13485 , 21 CFR 820 cGMP and 21 CFR 58 GLP compliance. Meanwhile，Mr. Yu has led the ISO 13485 compliance consulting for Stryker Great China Trading Company. This is the 1st Great China Trading Co. including mainland, HK, Taiwan multisite ISO certification in medical device trading co. business field and it significantly support the upcoming China GSP compliance.

Based on his language advantage and communication skill, Mr. Yu successfully support the Import Alert & FDA Warning Letter Clearance for the biggest Medical Device Company in Japan. In 2015, Mr. Yu support the Medtronic China facility to VAI accomplish the 1st FDA QSIT inspection.

Till 2016, Mr. Yu has consulted 63 FDA level II inspections, among them, 49 times were accomplished on NAI result with Zero defect, cases covers but not limited to Medtronic, Terumo, Acon, Andon, Neusoft, BD diagnostic, smith nephew, Zimmer-Biomet, JnJ – Depuy etc..

Meanwhile， through China CFDA start the oversea inspection, from the end of 2015, Mr. Yu was more and more involved the preparation of the upcoming oversea inspection by CFDA, so far three projects were experienced and Mr. Yu's work covers but not limited to:

- Let the manufacture get awareness of the composition of the Inspection team, coach the Chinese accompanying staff regarding to the QMS knowledge and let them know the basic knowledge of Annex IV in IVD, Annex II in MDD and QSR 820.
- Clarify how to use the CFDA regulation order 64 and 218 on-site inspection checklist
- Setup the war room and front room in the manufacturer and clarify its difference from USFDA inspection.
- Support manufacturer project team (CFDA inspection project) to do the gap analysis using the CFDA regulation
- The necessity review of performing on site mock audit
- Identify the potential translation candidate for upcoming inspector from their own staff team
- Develop the translation / interpretation skill for the translator.
- Review & support the preparation of the documentation required by the (MDL)Master Document List from CFDA

吴超儿，质量总监，江苏康诺医疗器械有限公司

Chaoer Wu, Quality Director , Conod Medical Co., Limited.

吴超儿现任江苏康诺医疗器械有限公司质量总监，11 年医疗器械法规符合工作经验，曾就职于浙江巴奥米特医药产品有限公司。在 2013 年和 2015 年期间主导应对了 4 次 FDA 检查，并独立完成了 FDA 483 的回复。

Carrie Wu, current Quality Director of Conod Medical Co., Limited. With 11 years regulatory compliance experience in medical device industry. Previously served in Zhejiang Biomet Medical Product CO., LTD. Carrie Wu has handled 4 FDA inspections in 2013 and 2015 and independently completed the FDA 483 response.

詹沛宇，国际事业部总经理, 浙江科惠医疗器械股份有限公司

Peter Zhan,General Manager, International Business of Canwell Medical

詹沛宇，有着丰富的工程技术背景和国际业务经验，这些年来，领导团队与世界各大骨科企业建立了广泛的业务关系与合作，并成为中国骨科器械领域最为优秀的企业之一。作为本土民营的骨科企业，不论是研发，供应链理念，还是生产运营的管理，尤其是法规质量体系，与国际一线的企业差距都是巨大的。这些年来，我们从对国际巨头的仰视到交流，从代工到伙伴，有许多值得分享的教训和心得。

With strong engineering background and international business experience, Peter leads his team building up broad and active collaborations with the world top Orthopaedics companies in the past decade. Now Canwell is becoming one of the best Orthopaedics instrument companies in China. As a domestic private enterprise, we still have huge gaps to catch up with the top international companies in terms of the R&D, supply chain, production management and quality & regulatory compliance system. Over the years, we've been through a lot during the transition, from simply looking up to the Giants to being able to cooperation, from contract manufacture to an important partner, there are many useful lessons and tips to share.

萨盾，驻华办公室助理主任，美国食品药品管理局

William M. Sutton,FDA Assistant Country Director, China, translation: Scott Yu

萨盾是在美国食品药品管理局（USFDA）国际项目办公室下属的 FDA 驻华办公室助理主任，他负责医疗器械的国际项目和政策分析。在被任命为 FDA 驻华办公室助理主任之前，萨盾先生是医疗器械和放射健康中心（CDRH）的行业与消费者教育处（DICE）副处长。他主要负责该处在医疗器械上市前喝上市后相关法规教育工作的战略发展。萨盾先生 1983 年起开始在 FDA 工作，曾在医疗器械评审办公室（ODE）和交流教育办公室（OCE）工作。在 FDA 工作期间，曾在 ODE 担任行政评审员，在 OCE 的企业和国际协助项目中担任消费者安全官主管。在这两项工作中，他负责国内和国际合规事务，并担任 FDA 第三方认可委员会（TPRB）主席，管理 510(k)评审的认可人员（AP）和现场检查的 AP。在过去的 21 年中，他参与了多国大量医疗器械相关联邦法规政策的培训。萨盾先生获得马里兰大学大学学院分校的科学管理学士学位。

William (Bill) Sutton is an Assistant Country Director in the Office of International Programs (OIP) at the United States Food and Drug Administration (FDA) China Office where he serves as the International Program and Policy Analyst (IPPA) for medical devices. Before being named Assistant Country Director of the FDA China Office, Mr. Sutton was the Deputy Director of the Division of Industry and Consumer Education (DICE) at FDA's Center for Devices and Radiological Health (CDRH) where he led the Division in the strategic development of regulatory education on medical device topics spanning premarket and postmarket policy. Mr. Sutton began his career at FDA in 1983, and has held positions in CDRH, the Office of Device Evaluation (ODE), and the Office of Communication and Education (OCE). During his tenure at the FDA he served as an administrative reviewer at ODE and as a Supervisory Consumer Safety Officer at the mandated industry and international assistance program in OCE. In both roles he worked on domestic and international compliance issues, and served as Chairman of FDA's Third Party Recognition Board (TPRB), which administered both the Accredited Persons (AP) for 510(k) review and AP for Inspection programs. For over 21 years he has educated the worldwide medical device community about Federal medical device regulations and policies. Mr. Sutton received a Bachelor of Science in Management Studies from the University of Maryland University College.

董何彦，主任委员、会长、董事长，全国心血管植入物分技术委员会、大连市医疗器械行业协会、辽宁垠艺生物科技股份有限公司

Dong Heyan, director,president, chairman, National Cardiovascular Implants Sub-Technology Committee, Dalian Association For Medical Devices Industry, Yinyi (Liaoning) Biotech Co., Ltd

董何彦，1958 年生于大连，国家二级教授，博士生导师。辽宁垠艺生物科技股份有限公司董事长、全国心血管植入物分技术委员会主任委员、大连市医疗器械行业协会会长。长期从事血管植/介入器械的技术研究和产品开发，在国内率先开发上市第一个无载体药物心脏支架、第一个冠脉药物洗脱球囊，多项技术填补国内空白。

Dong Heyan, born in Dalian in 1958, the national level two professor and doctoral supervisor. Yinyi (Liaoning) Biotech Co., Ltd chairman, director of the National Cardiovascular Implants Sub-Technology Committee, president of Dalian Association For Medical Devices Industry. Long engaged in vascular graft/ interventional devices technology research and product development, pioneered the development of the domestic market in the first carrier-free drug stent, the first drug eluting coronary balloon, a number of technologies to fill the domestic blank.

王瑾晔，教授、博士生导师，上海交通大学生物医学工程学院

Jinye Wang,professor , Ph.D. supervisor,Biomedical Engineering, Shanghai Jiao Tong University

王瑾晔，1992年获日本东北大学获博士学位，2000年9月起任中国科学院上海有机化学研究所百人计划研究员、课题组长。2009年3月起为上海交通大学生物医学工程学院教授、博士生导师。发表SCI论文80余篇，她引1000余次；获中国授权发明专利14项、美国国家专利1项；参编英文论著3本、主编英文论著1本、中文论著1本。在大型国际会议上做主旨讲演及邀请报告，包括2009、2010连续两年受邀在欧洲生物材料大会上做报告并担任分会主席。

Prof. Jin-Ye Wang, Ph.D (Tohoku University, Japan, 1992).

Professor of Shanghai Institute of Organic Chemistry, Chinese Academy of Sciences (2000-2009); professor of Biomedical Engineering, Shanghai Jiao Tong University (2009-).

Published over 80 SCI papers, 4 books (chapters);

authorized 14 Chinese patents and one US patent;

invited speaker of *European Conference on Biomaterials*, *Pacifichem* et al.;

awarded by the Hundred Talent Program of the Chinese Academy of Sciences (1999), Life Sciences Prize from Meiji Dairies Corporation (2008) et al.

Research interests: Tissue Engineering, Controlled Release and Fluorescent Probe, Biomimetic Materials and Biointerfaces.

宋晓东，高级研发工程师，创生（中国）医疗器械有限公司

Xiaodong Song, Sr.R&D Engineer, Trauson

宋晓东博士毕业于英国利物浦大学，毕业后任职于英国 LPW 金属粉末公司，任研发经理。2013 年底，宋晓东博士回国参加工作，任创生医疗高科技部高级研发经理，主导 3D 打印骨科领域的技术开发和生产工作。他主导开发的 3D 打印钛合金植入物，在保证安全稳定的物理性能同时，提供出众的初期稳定性和骨长入性能。同时，宋晓东博士受邀参与国内多家知名医院的研发合作项目，与国内知名骨科医生一起合作推广定制化骨科植入物的应用，致力于为广大国内外患者带来更高水准的骨科产品。

Dr. Song Xiaodong graduated from the University of Liverpool and worked as a research and development manager at LPW metal powder company in the UK. At the end of 2013, Dr. Song returned to China as a senior research and development manager in Trauson and focused on leading the research of 3D-printed titanium alloy orthopedics implants, which provide superior initial stability and bone growth performance while ensuring the safety and stability of the physical properties. At the same time, Dr. Song was invited to participate in a number of well-known domestic hospital development projects, cooperated with orthopedic surgeons to promote customized application of implants, committed to provide orthopedic patients with high-quality products.

汤亭亭，教授、博士生导师、实验室主任、骨科副主任，上海交通大学医学院、上海市骨内科植物重点实验室、上海交通大学医学院附属第九人民医院

Tingting Tang, Professor, Ph.D. supervisor, director, vice Director , Shanghai Jiao Tong University , Shanghai Key Laboratory of Orthopaedic Implants, Orthopedic Department of Shanghai Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine.

汤亭亭教授是上海市骨科内植物重点实验室主任、上海交通大学医学院附属第九人民医院骨科副主任，曾入选教育部新世纪优秀人才、新世纪百千万人才等培养计划。兼任国际华人骨研学会（ICMRS）候任主席、中国生物材料学会理事、全国生物力学专业委员会委员、中国骨科医师分会基础委员会副主任委员等职，并担任 Journal of Orthopaedic Translation、Bone Research、JBMR 等 16 本国际、国内杂志的编委等职。主要研究领域为骨科植入物和生物材料研究、干细胞及退变与再生研究、骨肿瘤研究等。已承担国家和部市级课题 30 余项，为国家重点研发计划首席科学家。已发表 SCI 收录论文 160 余篇（其中第一和通讯作者 66 篇），获国家发明专利授权 15 项。

Dr. Tang is professor, doctoral supervisor, director of Shanghai Key Laboratory of Orthopeadic Implants, vice Director of Orthopedic Department of Shanghai Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine. He had been awarded as candidate of New Century Excellent Talent Program of Ministry of Education, New Century Hundred, Thousand and Ten Thousand Talent Program in China. Currently he also serves President-elect of International Chinese Musculoskeletal Research Society (ICMRS), Board member of China Biomaterial Society, Committee member of China Biomechanics Society, Associate Committee Chairman of Chinese Orthopedic Research Society of CAOS, Editorial board members of over 15 international and Chinese journals including Journal of Orthopedic Translation, Bone Research, JBMR et al. His main research interests include orthopedic implants and biomaterials, stem cells research related to musculoskeletal degeneration and regeneration, cancer and bone disease. He had been the Principal Investigators of over 30 grants and currently is the leading scientist of National Key R&D program. He has over 160 peer-reviewed SCI indexed international publications and 15 authorized National invention patents.

贾冬杰, 博士，海外招商中心副主任，中国医药城

Winter Jia, Ph.D, Deputy Director of Business Development International Department ,China Medical City

毕业于中国农业大学，获得植物分子生物学博士学位，其专业背景为工作中更好的服务客户需求和了解日益更新的产品技术信息提供了良好的基础。主要致力于帮助国际生物技术公司落户中国市场、并扩展在中国的业务。毕业于中国农业大学，获得植物分子生物学博士学位，其专业背景为工作中更好的服务客户需求和了解日益更新的产品技术信息提供了良好的基础。主要致力于帮助国际生物技术公司落户中国市场、并扩展在中国的业务。

He is graduated from China Agriculture University and majored in plant molecular biology. Acknowledged for well-defined understanding of the molecular biology-technology and capacity to identify and align clients' emerging technology needs with products and services. His main interests are to introduce biotechnology companies to China and help them establish their operations. He has extensive resource and experience in helping companies get better communications with CFDA, Bureau of Industry and Commerce, Development and Reform Commission and investment agency.

刘青，董事长，北京阿迈特医疗器械有限公司

Qing Liu, CEO, Beijing Advanced Medical Technologies, Ltd. Inc

刘青，北京阿迈特医疗器械有限公司董事长/总经理，国家千人计划专家，同济大学先进材料与纳米医学研究院兼职教授， 同济大学附属东方医院纳米应用技术研究所副所长。

清华大学学士（1984）， 四川大学硕士（1987）， 荷兰 Twente 大学博士（1997）。 1997-2001 年间先后在美国 Rice 大学和 Temple 大学从事组织工程和生物材料研究。 2001 年起在美国 Therics 公司从事 3D 打印及个性化骨科修复产品研发。 2003 到 2007 年间 担任 Celgene 公司生物材料与干细胞研发总监。 2007 年在美国新泽西州创立 3D Biotek 公司，从事 3D 打印组织工程支架和 3D 细胞培养产品研发。2007 到起，作为 PI 先后承担过美国 NIH, NSF 和新泽西州科技委员会的 8 项课题。2011 年回国创立了北京阿迈特医疗器械有限公司，从事 3D 打印冠脉血管支架和外周血管支架的研发与产业化工作。

谭家宏，总经理，上海微创龙脉医疗器材有限公司

Jiahong Tan, General manager, Shanghai MicroPort Medical (Group) Co., Ltd.

谭家宏博士，现任上海微创龙脉医疗器材有限公司总经理、上海千人计划专家、四川大学和上海理工大学兼职教授；于加拿大麦克马士德大学获得博士学位，美国生物材料学会、美国化学学会会员，在北美从事生物材料和医疗器械领域研发生产工作长达十六年；出国前已是中国医学科学院的副研究员，中国协和医科大学的硕士导师，1996 年以高级访问学者的身份留学美国；2003 年至 2012 年，先后担任美国圣尤达医疗用品有限公司资深科学家及美国强生公司首席工程师；2012 年 10 月出任上海微创电生理医疗科技有限公司的技术副总裁；现任上海微创龙脉医疗器材有限公司总经理。

Urs Mattes,董事总经理，CENDRES+METAUX

Urs Mattes ,MD, CENDRES+METAUX

General Management Executive with more than 20 years of cross-functional expertise in profit and non-profit. life science companies throughout Asia-Pacific, Europe and Middle East. A leader that guides, energizes and excites his team to excel and that is capable to balance the interests of all stakeholders. A good listener and openminded person living up to high ethical standards and integrity associated with a strong sense of honesty and fairness are core values.

General Management Executive with proven ability to turn around failing operation of a Swiss family-owned medical device company and become the leader in the orthopedic trauma market in China as late entrant with outstanding track records in sales and profits. Succeeded in building for the leading non-profit Foundation in orthopedic postgraduate education and innovation the Asia-Pacific operation with the fastest growing network of surgeons and the most attractive CME accredited program.Skilled in direct sales channels and distribution network development, marketing and product life cycle management, guidance of innovation projects, regulatory & scientific affairs, and planning phase of manufacturing operation.

- Multi-cultural background
- Strong blend of business experience and medical / scientific background
- Familiar with orthopedics, dental and imaging and other fields in medtech
- Experienced in reporting to Board of Directors
- Board Member experience
- Senior Advisor China Medical Cluster Switzerland
- Lived and worked in Europe and Asia
- Fluent in German, English, French, basic Mandarin

戴一非，董事总经理，IDC 中国

Yifei Dai, Managing Director, IDC China

戴一非，IDC 中国董事总经理，拥有超过 15 年的产品研究与开发及品牌商业化经验 。作为 IDC 中国的创始人之一，她以其在英国创新行业多年的工作经验，带领 IDC 设计及工程团队帮助中国医疗企业进行产品创新，并成功实现品牌的升级。IDC 在过去几年，成功实现了如具有突破性创新的足下垂助行仪、全国首例医用胶给液笔及荣获红点至尊奖殊荣的电子可视喉镜等优质医疗设备。

Dai Yifei, Managing director of IDC China, with over 15 years' experience in prodcct research, development and brand commercialisation, including many years work experience within the UK innovation industry. As the founding member of IDC China, Fei has led the IDC design and development team alongside Chinese manufacturers to create innovative products and upgrade their brands successfully. During the past few years, IDC has successfully created outstanding medical devices such as a breakthrough innovative G3 footdrop device, the first medical glue dispenser in the China market and an electric laryngoscope which achieved the Reddot best of the best award.

朱志兴，高级产品经理，金雅拓软件货币化事业部

Zhixing Zhu, Senior Product Manager, Software Monetization Business Unit of Gemalto

丁晨彦 ， 高级应用开发工程师 ， 3M

Yann Ding ,Senior Application Development Engineer ,3M

2007 年毕业于里昂第一大学，并获得聚合物材料学专业硕士学位。

2011 年加入 3M 中国有限公司，任职于 3M 中国研发中心。

作为 3M 医疗产品事业部高级应用开发工程师，主要负责医用材料与技术部门的产品应用与开发，中国区业务的技术支持等工作。

2011 年至今，已取得 2 项国内发明专利与 1 项国际发明专利授权， 并正在参与 1 部胶粘剂专业著作的编撰。

Mr. Yann Ding graduated from University Claude Bernard Lyon 1 of Science & Technology with a Master Degree majoring in Polymer Materials in 2007. He joined 3M as an Advanced Application Development Engineer for Health care – Medical Materials & Technologies in 2011.

Since joined in 3M, he took over the role of leading the application development & technical support for 3M Medical Materials & Technologies business in China, and to be the contact person for 3M global Medical Specialties technical team. Yann authored two local patent filing and one global patent filing and he is participating in the preparation of a book focus on adhesive.

冯晓明，研究员&副主任，中国食品药品检定研究院生物材料和组织工程室

Xiaoming Feng, Researcher & Deputy Director, Division of Standardization & Science Research, Institute for Medical Devices Control, National Institutes for Food and Drug control (NIFDC)

冯晓明，中国食品药品检定研究院研究员，生物材料和组织工程室副主任，从事医疗器械检验和检验方法学研究，获得省部级科技二等奖三项，主持国家 863 重大专项”干细胞与组织工程技术标准研究“等课题 3 项，参与国家自然科学基金、国家 863 和北京市科技项目 6 项，组织制定医疗器械国家标准、行业标准 36 项。 兼任中国仪器仪表协会分析仪器分会常务理事 、国家食品药品监督管理局医疗器械产品注册评审专家、医疗器械生产质量管理规范（GMP）检查员，国家药品标准物质委员会委员 ，全国医疗器械生物学评价标准化技术委员会委员等职。

Feng Xiaoming, Researchers in the National Institutes for Food and Drug control (NIFDC), vice director of biomaterials and tissue engineering division, engaged in the research of medical equipment inspection and testing methodology, won the three prize of provincial and ministerial level science and technology, presided over the National 863 projects "stem cells and tissue engineering technique standard issue of" 3, participate in the National Natural Science Foundation of China, National 863 and the Beijing Municipal Science and technology project 6, organize of national standards of medical devices, the industry standard 36. As China Instrument Association executive director, analysis instrument branch of State Food and Drug Administration medical device registration evaluation experts, medical equipment production quality management specification (GMP) inspectors, a member of the National Committee of national pharmaceutical standard material, biological evaluation of medical devices Standardization Technical Committee and so on.

周贵，法规技术部总监，捷通集团

Noble Zhou,Technical Director of Regulatory Affairs, Jyton Consulting

周贵，毕业于北京科技大学生物医用材料专业，硕士学位。现就职于捷通集团任法规事务部——技术总监，兼任公共事务与资源开发部总监，从事医疗器械法规事务咨询 6 年。特别擅长编写各种产品的技术要求和检测方法，参与过国家行业标准的制定研讨；有大量的注册检测实践经验。曾分别在中国药品生物制品检定研究总院、上海医疗器械高等专科学校、SGS 通标标准技术服务有限公司担任重要职务。

曾毅，总经理兼技术总监，东易中美科技（北京）有限公司

Yi Zeng,General manager& technical director, Doeasy Sino – US Technology (Beijing) Co., Ltd

曾毅博士，毕业于美国俄亥俄州立大学. 从本科到博士后研究都是和生物材料相关的领域，博士后研究更是在领域中的国际知名试验室，从师于世界知名心血管专家，并发表多篇学术论文。其掌握医疗器械和生物医药的核心技术，并拥有独立自主知识产权，技术成果领先，能够填补国内空白，是具备良好市场潜力和产业化条件的科技创业领军人才。曾毅博士先后任职于世界最顶尖的医疗器械厂家，从事各种支架的技术开发和研发管理，对支架等介入类产品的研发和生产的每一环节都非常精通；曾毅博士参与开发的支架已在市场上广泛使用，这些产品包括主动脉血管覆膜支架、外周血管自膨支架、冠状动脉分叉支架等，经他研发生产的支架在形态设计和药物涂层工艺方面拥有多项美国及欧州专利。在胸主动脉和腹主动脉覆膜支架的研发、生产和质量管理上，曾毅博士更是有着拔尖的理论基础和实践经验。他先后参与和主导了美国 Boston Scientific (波士顿科学)公司的腹主动脉覆膜支架(Vanguard)和美国 Medtronic(美敦力)公司的腹主动脉覆膜支架(AneuRx)的研发和生产。Vanguard 支架是世界上第一个进行临床试验的腹主动脉覆膜支架，而 Medtronic 的 AneuRx 支架则是第一个通过 FDA 认证的腹主动脉覆膜支架，其国际市场占有率曾超过 90%。

秦蕾 ，资深技术市场经理，杜邦

Ms. Selena Qin，Senior Technical Marketing Manager,Dupont

加入杜邦医疗包装防护部之前，秦蕾女士是一位拥有 10 多年经验的临床医生，她从专业的角度突显医疗产品无菌的重要性，帮助亚洲不断增长的医患提供高质量的护理。

Before joined DuPont Medical & Pharmaceutical Packaging (MPP) team, Selena had more than 10 years of experience in medical device industry; In DuPont, Selena is focusing on driving regional technical marketing and application development programs for MPP, as part of DuPont's initiative to accelerate demand creation efforts for Tyvek® Medical Packaging in Asia.

Luc VanderBroeck，药品医疗器械包装膜应用经理，科佩欧洲药包膜事业部

Luc VanderBroeck, Application Manager Pharmaceutical & Medical Device Films, Klöckner Pentaplast Europe Pharmaceutical Films Division

Luc 拥有 25 年在聚合物及塑料行业广泛应用领域的经验。最早任职于荷兰的帝斯曼公司，在多种聚合物更广泛的应用领域从事生产和开发工作。于 1998 年获得分析化学的理学学士学位后，Luc 加入了科佩，担任一般包装聚酯薄膜的应用工程师；为使用一般包装薄膜的客户提供应用支持，以及开发应用于医疗和防静电包装的薄膜。2002 年从 Eindhoven 大学博士后研究生毕业后，在接下来的几年中 Luc 在多种塑料包装应用的技术支持和市场营销的角色中转换岗位。目前，他已晋升为药品医疗器械包装膜的应用经理，为所有客户提供支持以选择和使用最适合他们产品应用的包装材料，以及为医疗器械包装探索和开发新的应用。

With 25 years of experience in polymers & plastics in a wide variety of applications Luc started with the Dutch company DSM for production & development of a wide variety of polymers in an even wider field of applications. After solving a BSc in Analytical Chemistry, in 1998 Luc joined Klöckner Pentaplast in his role as application engineer for Polyester films in general packaging; supporting customers in the application of films for general packaging, and developing films for Medical and Antistatic packaging-applications. In 2002 receiving a post-doc graduate in Polymers from the University of Eindhoven, the following years Luc switched several positions in the technical support and marketing for a wide variety of plastic packaging applications. Currently his role has developed to Application Manager for Pharmaceutical & Medical Device packaging films. In this role supporting all customers with their choice and usage of the best to fit packaging material for their application, as well as exploring & developing new applications for Medical Device packaging.

Kevin Zacharias，技术总监，苏州奥力拓

Kevin Zacharias, Technical Director ,Oliver™ Healthcare Packaging

Kevin Zacharias is the Technical Director at Oliver Healthcare Packaging in Grand Rapids, MI where he is responsible for product development and technical service.

Kevin earned a BS degree in Packaging from Michigan State University and an MBA from Butler University. He has over 25 years of experience in the medical device packaging industry with a focus in package design, validation and product development. His previous employment included the positions of Manager of Packaging Development at Baxter Healthcare and Packaging Engineer at Roche Diagnostics.

陈强，总经理，上海金鹏源辐照技术有限公司

Qiang Chen, CEO, Ion-Tech

陈强，上海金鹏源辐照技术有限公司总经理，专业从事伽玛辐照加工 30 余年，一直专注于伽玛辐照装置建造、剂量分布研究、医疗保健产品辐射灭菌；全国消毒技术与设备标准化技术委员会（SAC/TC200）委员，GB18280-2015 标准起草人之一，中国同位素与辐射行业协会专家咨询委员会委员，上海市核学会辐射工艺及辐射加工专业委员会副主任委员。

John Chen, General Manager of Shanghai JPY ION-TECH., Co., Ltd., specializes in Gamma Irradiation processing more than 30 years, focuses on construction of Gamma

Irradiator, dose distribution study and radiation sterilization for healthcare product.
John Chen, the member of National Technical Committee 200 on Sterilization Techniques and Equipment of Standardization Administration of China (SAC/TC200), the member of Standard Drafting Team for GB18280-2015, the member of Expert Consultation Committee of China Isotope & Radiation Association, and the member of Radiation Specification And Radiation Processing Committee of Shanghai Nuclear Society.

张其清，博士、博导，中国医学科学院生物医学工程研究所

Qiqing Zhang, Ph.D., Ph.D. supervisor ,Institute of Biomedical Engineering, Chinese Academy of Medical Sciences

厦门大学化学系毕业；天津大学获生物医学工程学博士学位；中国医学科学院、北京协和医学院生物医学工程研究所二级研究员、博士生导师、所学术委员会副主任；加拿大多伦多大学药学院和芬兰亚拓大学科学与技术学院访问教授；福州大学生物和医药研究院院长，曾任厦门大学生物医学工程研究中心主任、材料学院和医学院副院长。兼任中国纳米生物材料专业委员会主任委员、福建省国际人才交流协会常务副会长、国际 TC-194 成员、中国生物材料学会理事、全国标准化技术委员会委员等国内外 40 多个学术机构的负责人、常务理事等；JAMS、Biomaterial 等 30 几个杂志的常务编委、编委或审稿专家；科技部、国家科技奖、基金委、教育部、卫生部、发改委、国家药监局等的评审专家。

致力于由创伤、肿瘤和退行性病变等导致的临床病缺损再生修复、诊断和防治功能、智能型医用生物材料研究近 40 年。作为课题负责人，结合材料科学、临床医学、生物医学工程学、药学、纳米技术、3D 打印技术、干细胞和生物技术等承担过国家自然基金重大研究计划、863、973（子课题）、国家支撑计划、国家重点新产品计划和国家火炬计划及国家杰出青年基金等 100 多项。发表的论文 460 篇被 Chem Rev（IF 37.37）等引用 7121 次，授权发明专利 104 项，合作转让合同金额及引资 2 亿多元，获三类医疗器械注册证 8 个、卫生产品许可证 1 项；主编和参编论著及指南 10 部；北京协和医院等单位应用本人的成果发表了 169 篇论文并给予高度评价；50 多次在应邀的国内外学术会议和作为大会主席组织的学术会议上做报告，成果得到同行认可并入选基金委建国五十周年《优秀应用推广成果项目选编》。培养博士后 2 名，博士生 47 名，硕士生 137 名。为国家从欧洲引进 6 名高层次专家分别受到李克强总理、福建省于伟国省长、国家外国专家局张建国等的接见并被授予福建省政府友谊奖等。

创建了中国医学科学院生物材料与人工器官研究室、天津市生物医学材料重点实验室、厦门大学生物医学工程研究中心、福建省高校生物医学工程重点实验室、厦门市生物医学工程技术研究中心、福州大学生物和医药技术研究院、新乡医学院生命科学与健康研究院、福建吉特瑞生物科技有限公司和福建省博特生物科技有限公司等。

获得中国产学研合作创新成果一等奖、发明创业奖人物奖特等奖、教育部技术发明二等奖、卫生部科技进步二等奖、天津市自然科学二等奖和天津市发明专利金奖科技奖等 18 项。享受国务院政府特殊津贴、获首届全国优秀科技工作者、第二届全国中青年医药科技之星、全国百千万人才工程第一层次人选，七次被评为中国医学科学院北京协和医学院先进、优秀教师，四次被评为天津市教卫委和中国医学科学院等优秀共产党员，还被评为第二届天津青年科技奖、天津市“五一”劳动奖章、第二批福建省高层次创新创业人才、中国当代发明家，还被授予中国医学科学院杰出贡献奖（院校成立 100 年共 20 名）等二十多个荣誉称号。曾三次在人民大会堂收到党和国家领导人的接见。厦门大学化学系毕业；天津大学获生物医学工程学博士学位；中国医学科学院、北京协和医学院生物医学工程研究所二级研究员、博士生导师、所学术委员会副主任；加拿大多伦多大学药学院和芬兰亚拓大学科学与技术学院访问教授；福州大学生物和医药研究院院长，曾任

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冯桂强，市场总监，Sabic

Frank Feng, marketing manager, Sabic

现任沙特基础工业公司（SABIC）医疗行业中国区市场经理，1998 年大学毕业，高分子材料与工程专业。2001 年加入 SABIC（2008 年之前属于 GE 塑料集团）公司，先后担任过技术工程师、市场开发，销售经理等不同角色，目前主要负责公司在大中华区医疗行业的市场开发。

Healthcare industry marketing manager of SABIC; He graduated in 1998 and his major is high polymer material and engineering. Frank joined SABIC(it belonged to GE plastics before 2008) in 2001, he has experienced in technical engineer, marketing development, and sales manager etc. Frank is responsible for the healthcare market development in greater China now.

李兆敏博士，精密管材技术中心总监，上海微创医疗器械（集团）有限公司

Kevin Li, Director of Precision Tube Center, Precision Tube Center of MicroPort

李兆敏博士现任上海微创医疗器械（集团）有限公司精密管材技术中心总监，专注于介入医疗器械用精密管材成型技术，各种医用高分子管材是介入医疗器械的关键组成部分，所涉及的产品覆盖了心血管介入产品、电生理导管、大动脉及外周血管介入产品、神经介入产品及介入配件产品。

Dr. Li Zhaomin is currently Director of Precision Tube Technology Center at Microport Medical. His main interests focus on the process technology of precision medical tube for invasive medical device. Many kinds of precision medical tubes including balloon tube, braid reinforced tube, coil reinforced tube, multi-lumen tube, multi-layer tube, bump tube, are widely used in Invasive Medical Devises. The relative products cover from Cardiovascular Devices, Endovascular Devices, Electrophysiological Devices, Neurovascular Devices and so on.

Chew KahMeng，医疗电子市场经理，是德科技 GEMS 市场部

Chew KahMeng , Medical electronics market manager , Marketing Department of Keysight

T.K. Wong (KW), Vice President, Technical Center Asia 利奥电池
T.K. Wong (KW), Vice President, Leo power Technical Center, Asia
拥有 Inventus Power 26 年的技术和领导经验；在中国清溪成立第一条 SMT 线和自动插入线；成立亚洲产品开发和工程团队；在中国广州开设技术中心；中山大学工程学士学位；拥有多项专利。
26 years of technology and leadership experience with Inventus Power; stablished first SMT line & Auto Insertion Line at Qingxi, China facility;ounded Asia Product Development & Engineering team ;ened the technical center in Guangzhou, China;ngineering degree from Sun Yat-Sen University;olds several patents

裴科培，马斯科特电源设备（宁波）有限公司
Jerome Pei, General Manager, Mascot Power Supplies (Ningbo) Co.,Ltd

史佳良，CEO，上海鹊宁管理咨询有限公司
Lawrence Shi，CEO ,Quality Training
毕业于同济大学工业工程硕士，曾任职于阿尔卡特朗讯、施耐德电气等 500 强外资企业，拥有 15 年丰富的供应商质量管理经验。目前转型从事第三方供应商质量管理，为部分客户提供第三方的质量管理解决方案。并开发了基于 SAAS 的企业质量数据分析系统，能更好的帮助供应链上下游进行及时赫尔有效的共沟通。
Graduated from Tongji University, master of industrial engineering, who have served in the top 500 foreign companies such as alcatel lucent, Schneider electric, with 15 years rich experience in supplier quality management. Currently working on a third party supplier quality management, for part of the customer to provide third party quality management solution. Also develop the enterprise quality data analysis system based on SAAS, can better help timely and effective communication in upstream and downstream of supply chain.

郝霞，法规产品经理，美敦力大中华区研发中心
Xia Hao, Regulatory product manager,
11 年医疗器械生产研发企业注册和质量相关工作经验，曾担任微创神通品质注册资深经理，管理者代表，现任美敦力大中华区研发中心法规产品经理。 ASQ SHLMC Expert；精通 CFDA、FDA 和欧盟的医疗器械法规要；曾在“医疗器械从业者”微信公众号发表多篇文章

施小立，CEO，深圳市领先医疗服务有限公司

Lily Shi, CEO , Shenzhen Advanced Medical Service Co., Ltd.

生物材料博士。10 年高风险医疗器械法规和质量管理工作经验。熟悉心血管植入器材的全球注册、临床、临床前测试、质量体系；参与设计开发、质量管理、临床研究及注册上市全过程，逾百个产品成功上市经验；作为主要负责人为企业成功申请中国创新医疗器械取得认可 7 个，起草国家及国际标准 4 个，负责多个欧盟、中、美临床试验，编写临床评价并成功获批 30 余个，作为讲师对内部及外部培训 100 余场次，内审及外审陪同 50 余次。

Bio-material PhD. 10 years experience in High risk medical device regulatory and quality management. Familiar with cardiovascular implant device global regulatory, clinical, preclinical testing and quality system.

卫根学， 副主席、专家、国际注册质量工程师、国际注册六西格绿带、国家软件评测师中级工程师 ，ASQ 北亚区上海会员社团考试认证部，ASQ SHLMC

Genxue Wei，Vice chairman，Expert，CQE，GB，National Software Evaluator Intermediate Engineer，ASQ North Asia Shanghai Member Association Examination and Certification Department，ASQ SHLMC

12 年以上生产研发型企业医疗器械质量相关工作经验曾担任某上市公司质量总监，管理者代表，高级 QMS,某集团 QMS 审核工程师、QMS 经理、质量经理等职务，精通 CFDA 医疗器械法规和 ISO 13485、ISO14971 熟悉世界主流国家（QSR 820、KGMP、JGMP、BGMP）医疗器械质量管理体系法规要求。2015 年主编出版了《医疗器械产品分类指南》一书；2016 年创建并运营“医疗器械从业者 MDP”微信公众号；2017 年成为工业采购宝特邀高级讲师。目前专注研究方向：医疗器械质量管理体系与法规的应用与实践。提供质量管理体系与法规方面的咨询与服务。

Valery Perevalov, CEO of ANV Laser Industry Ltd., Israel

Precision laser cutting and laser welding . Advanced thermal treatment. Chemical and electrochemical solution.Bench testing. Rapid response department.

毛化，咨询总监，弗若斯特沙利文咨询

Fred,Consulting Director,Frost & Sullivan

Fred is the Consulting Manager of Healthcare Group of Frost & Sullivan China， has 4 years of consulting and market research experience. He has particular expertise in:

- New market entry strategy: market trends analysis， market segmentation， Chinese market research， foreign company localization strategy & implementation.
- Industry analysis: competitor analysis， new product launch， Chinese Medical policy analysis， opportunities in new marketplace.
- Experience and insights in a bunch of industries: medical device， medical imaging， pharmaceutics， biotechnology and healthcare service

孙德岚，董事总经理，艾意凯咨询公司

Stephen Sunderland ,Managing Director ,L.E.K. Consulting

孙先生拥有剑桥大学制造工程学工程学硕士学位。在过去 16 年，孙德岚先生作为中国和欧洲的公司战略专家，在生命科学、医疗器械和健康服务领域领导并制定了多个切实可行的公司增长战略。孙先生对政府、政府企业、世界顶级企业、创业者和金融投资者的广泛领域客户提供战略决策服务。孙德岚先生于 2001 年加入艾意凯咨询公司伦敦办公室。2005 年孙先生曾在中国办公室工作，并于 2011 年正式调任艾意凯咨询公司上海办公室工作。在欧洲和中国，孙先生有广泛的业务增长和兼并收购战略咨询经验，买方和卖方商业尽职调查，商业投标和诉讼支持咨询经验。

Stephen holds a Master of Engineering in Manufacturing Engineering from the University of Cambridge.During the last 16 years as a corporate strategy advisor in China and Europe, Stephen has led the development of pragmatic, implementable growth strategies across the Life Sciences, MedTech and healthcare services sectors in China. Stephen has provided strategic decision support for a range of clients, including government / government controlled entities, some of the largest and most complex enterprises in the world, as well as more entrepreneurial businesses, and financial investors.Stephen Sunderland joined L.E.K. Consulting's London office in 2001. In 2011, Stephen transferred to L.E.K.'s Shanghai office after previously spending time in L.E.K.'s China offices in 2005. In Europe and China, Stephen has consulting engagement experience in organic and inorganic strategy development, commercial due diligence (buy side and sell side), commercial bid support and litigation support.

陈盈松，技术总监，西门子工业软件医疗行业技术总监

Alan Chen, Technical director, Siemens PLM

范立新，技术经理，西门子工业软件医疗行业

Fan Lixin, Technical Manager, Siemens PLM

张志成，技术经理，西门子工业软件医疗行业

Jerry Chang, Technical Manager, Siemens PLM

王尧民，采购总监，上海微创龙脉医疗器材有限公司

Raomin Wang, Purchasing Director, MicroPort

•2016.6 月　微创医疗资深采购总监；
•2014 年 2 月至 2016.6 月，青岛海尔集团全球采购总监，主管集团采购和供应链工作；
•2010 年聘为上汽工程学会采购专家组成员；
•2008 年-2014 年，负责上汽海外采购和供应链网络的建设；2006 年-2008 年任联合汽车电子采购经理，主管工厂生产采购、物流供应链及信息化，2008 年工厂产能实际产能达到 1800 万 Injector，5 月产创历史新高；
•经历过中美合资，中德合资，从汽车到家电再到医疗，美国企业，德国企业，国营公司不同企业文化的碰撞。

谭家宏，总经理，上海微创龙脉医疗器材有限公司
Jiahong Tan, General manager, Shanghai MicroPort Medical (Group) Co., Ltd.

谭家宏博士，现任上海微创龙脉医疗器材有限公司总经理、上海千人计划专家、四川大学和上海理工大学兼职教授；于加拿大麦克马士德大学获得博士学位，美国生物材料学会、美国化学学会会员，在北美从事生物材料和医疗器械领域研发生产工作长达十六年；出国前已是中国医学科学院的副研究员，中国协和医科大学的硕士导师，1996 年以高级访问学者的身份留学美国；2003 年至 2012 年，先后担任美国圣尤达医疗用品有限公司资深科学家及美国强生公司首席工程师；2012 年 10 月出任上海微创电生理医疗科技有限公司的技术副总裁；现任上海微创龙脉医疗器材有限公司总经理。

姜洪焱，研发技术支持与共享副总裁，上海微创龙脉医疗器材有限公司
Hongyan Jiang, Vice president of R & D and Technical Support and sharing, MicroPort

高分子材料理学博士、上海微创医疗器械（集团）有限公司研发技术支持与共享副总裁、上海微创医疗集团双十领军人才、浦东新区百人计划专家、上海理工大学食品与医疗器械学院兼职教授；回国加入微创医疗之前在美国和德国从事生物材料与医疗器械研发 13 年，曾担任德国 mNemoscience 医疗科技公司项目经理和研发部门负责人；在包括《自然》等学术核心期刊上发表学术论文 20 多篇，编写英文专著一部，申请发明专利近 20 篇。

赵瑞辉，冠脉导管研发经理 ，上海微创龙脉医疗器材有限公司
Ruihui Zhao, Coronary Catheter R & D Manager, MicroPort

王常春，手术机器人研发经理 ，上海微创龙脉医疗器材有限公司
Changchun Wang, Surgical robots R & D Manager, MicroPort