【严樑】，上海浦东医疗器械贸易行业协会会长、上海医疗器械行业协会副会长，上海食品药品监督管理局食品药品安全研究中心政策法规和国际合作资深顾问。曾任上海食品药品监督管理局医疗器械注册处处长、政策法规处处长、国际合作处处长。改革开放前任上海市医药管理局科技处长。2008 年从公务员岗位退休。具有 30 多年医疗法规管理和医药工业管理工作经验。1989 年起草了中国第一个医疗器械监管法规。2006 年提出采用唯一标识/UDI 在上海完成了 120 家医院的植入医疗器械追溯试点。2009 年领导中国医疗器械命名转化研究小组完成了第一次全球医疗器械命名数据库/GMDN 的转化工作。是全球医疗器械协调组织 UDI 特别工作组成员，曾任第一届亚洲医疗器械协调组织医疗器械命名和唯一标识特别工作组（STG）主席。2011 年荣获全球医疗法规组织 RAPS《全球医疗法规领导者奖》。2016 年全球物品编码标准组织 GS1 组织授予他全球医疗供应链贡献奖。

Yan Liang, President of the Shanghai Pudong Medical Device Trade Association; Vice President of Medical Devices Industry Association; Senior Consultant of policy & regulations and international cooperation in Institute of Food and Drug Safety of Shanghai Food and Drug Administration. He served as the former Director of Medical Device Registration and Director of Legal Affairs and International Affairs of Shanghai Food and Drug Administration. He has retired from civil servant position in 2008. He has been engaged in the government administrative work for more than 30 years, focusing on the pharmaceutical and medical device industry management and administrative regulations area. He led to drafted the first China medical device regulation in 1989. In 2006, he used UDI concept to organize a first pilot project of the implantable medical device traceability system in Shanghai 120 hospitals. In 2009, he headed China medical device nomenclature translation research group to complete the first Chinese version of GMDN (global medical device nomenclature). He was a member of GHTF AHWG UDI, as well as the first chairman of AHWP STG for device naming and coding harmonization in Asia. He received a Global Leadership Award in 2011 from Regulatory Affairs Professional Society (RAPS). He received the Global Contribution of Medical Supply Chain Award from GS1 the global organization of article number in 2016.

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.

Thomas Jaw 医学经理，能盛(上海)

Thomas Jaw Medical Research Manager, NAMSA

赵家骥博士在医药产业及医疗器械产业有超过十年的经验。其中包含动物模型建立，药理学研究，药物及医疗器械的临床研究。专注于 CFDA，US FDA 和欧洲的药物及医疗器械上市的产品上市途径规划。近年，赵博士加入医疗器械产业专注于临床试验方案设计及法规咨询，并曾担任数个为了 CFDA 审批的多中心临床试验的项目经理，负责设计及主笔临床试验方案。专长的邻域包含骨科，透明质酸钠，伤口愈合贴片，外科粘合剂，人工晶状体及体外诊断试剂。以及利用境外临床试研结果应用在 CFDA 或是 US FDA 将产品注册上市。

内容摘要：

跨国使用临床数据进行医疗器械审批能够节省大量的时间和花费，CFDA 出台接受医疗器械境外临床试验数据技术指导原则之外，US FDA 也有类似的指导原则接受境外临床数据。赵博士将分享使用境外临床试验数据递交审批的具体作法及合理的途径。

美国 FDA 对于接受境外临床数据的指导原则

使用境外临床试验数据在美国注册的常见问题

使用境外临床数据在 CFDA 注册的考虑

合理的途径

How to support product registration with foreign clinical data, from China to US and from US to China

Dr. Thomas Jaw had focused on the pharmaceutical and medical device industry for more than 10 years with comprehensive expertise of animal disease modeling, preclinical

pharmacology and toxicology studies and clinical studies. He focused on the product development planning for pharmaceuticals and medical device in CFDA, US FDA and Eurpoe. Recently years, Dr. Thomas Jaw joined medical device industry and focused on clinical protocol design and regulatory consulting. He is currently responsible for the protocol design of several multi-site clinical studies for CFDA submission. Expertise fields include orthopedic replacements, hyaluronic acid products, wound patches, surgical adhesive products, intraocular lenses and IVDs, and application of foreign clinical to support product registration in CFDA or US FDA.

Using foreign clinical data for medical device registration could save a lot of time and expenses. CFDA issued a guidance to accept foreign clinical data for medical device registration lately, Also, US FDA had guidance for foreign clinical data. Dr. Jaw will share the experience of using foreign clinical data for medical device registration and the practical pathway and considerations.

US FDA guidance of acceptance of foreign clinical data for medical device
Frequently asked question for using foreign clinical for US FDA registration
Consideration of using foreign clinical data to register in CFDA
Practical pathway

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 25 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。

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,67 次 FDA 21CFR820 的现场 QSIT 检查经历和 6 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 2018 年， 虞则立先生已经完成了 67 例 FDA 工厂检查的现场陪同工作，其中 53 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， 其中特别是有在 2017 年，虞则立先生在美国以零缺陷协助完成了 III 类产品 PMA 的检查

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，目前已积累八个项目的经验，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

2017 年起，虞先生被国家食品药品监督管理总局高级研修学院任命为海外检查官课程讲师，特聘专家，负责教授检查技巧。

Graduated from the Medical College Affiliated to Shanghai Jiao Tong University, in his 25 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.

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）, 67 times FDA 21 CFR 820 on site QSIT experience and 6 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 2018, Mr. Yu has consulted 67FDA level II inspections, among them, 53 times were accomplished on NAI result with Zero defect, cases cover but not limited to Medtronic, Terumo, Acon, Andon, Neusoft, BD diagnostic, smith nephew, Zimmer-Biomet, JnJ - Depuy etc.，specifically in 2017, Mr Yu assisted a Class III Device PMA preapproval inspection in US with NAI result with Zero defect.

Meanwhile， through China CFDA start the oversea inspection, from the end of 2015, Mr. Yu was involved the preparation of the upcoming oversea inspection by CFDA, so far 8 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 it’s 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
….
In 2017, Mr.Yu was appointed by CHINA FOOD AND DRUG ADMINISTRATION INSTITUTE OF EXECUTIVE DEVELOPMENT as the tutor for the CFDA oversea inspector to coach the inspection skill.

卫根学 生物医学工程专业，ASQ（美国质量学会）高级会员，ASQ 国际注册质量工程师 CQE，ASQ 国际注册六西格绿带 GB，国家软件评测师中级工程师

12 年以上医疗器械生产研发型企业质量相关工作经验，曾担任某上市公司质量总监，某集团 QMS 审核工程师、某公司 QMS 经理、某公司质量经理兼管理者代表职务，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）的体系法规要求，已有多家企业辅导经验和企业的长期顾问。
2015 年主编出版了国内第一本《医疗器械产品分类指南》
2016 年创建 “医疗器械从业者 MDP”微信公众号
2017 年成为“工业宝”特邀高级讲师
2018 年成为医疗器械行业自由职业者

Yvonne Leonard 市场主任，药明康德测试事业部
Yvonne Leonard, Director of Marketing, WuXi AppTec Laboratory Division

Yvonne Leonard 有超过 20 年在医疗器械，医药和生物制药产品领域的经验，有丰富的产品服务及新产品发布的成功经验。
Leonard 女士担任产品经理，负责新产品开发，开发新的分销渠道和产品生命周期管理。她在全球慢病管理领域与医生和疾病管理联盟合作，并成功游说全球肺病组织，将医疗器械的使用纳入 COPD 指南。其他亮点包括波士顿科学药物洗脱支架 TAXUS 的推出，该团队成功地在 80 天内获得了市场 80%的份额——被认为是设备史上最成功的产品发布之一。
目前在药明康德美国负责新服务产品。她帮助 FDA 开发了成功的教育项目，并继续将客户的需求带入前沿，以建立新的伙伴关系和解决方案。Leonard 女士持有明尼苏达大学的学士学位。
With more than 20 years of experience in marketing medical devices, and pharmaceutical and biopharmaceutical products, Yvonne Leonard brings a proven track record of successful product and service launches to the industry.
Ms. Leonard has worked as a group product manager responsible for new product development, developing new distribution channels and product life-cycle management. She has partnered globally with physicians and disease management coalitions in the area of chronic disease management, and successfully lobbied the Global Organization for Lung Disease to recognize and incorporate the use of a medical device into COPD guidelines,

which were formally only pharmaceutical. Other career highlights include the launch of the Boston Scientific drug-eluting stent TAXUS, where the team successfully penetrated 80 percent of the market and gained 80 percent share in 80 days - considered one of the most successful product launches in device history.

In her current role at WuXi AppTec, Ms. Leonard is responsible for current and new service offerings. She has developed successful educational programs for the FDA, and continues to bring the needs of customers to the forefront to establish new partnerships and solutions. Ms. Leonard holds a bachelor's degree from the University of Minnesota.

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.

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 25 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。

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,67 次 FDA 21CFR820 的现场 QSIT 检查经历和 6 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 2018 年， 虞则立先生已经完成了 67 例 FDA 工厂检查的现场陪同工作，其中 53 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， 其中特别是有在 2017 年，虞则立先生在美国以零缺陷协助完成了 III 类产品 PMA 的检查

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，目前已积累八个项目的经验，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

2017 年起，虞先生被国家食品药品监督管理总局高级研修学院任命为海外检查官课程讲师，特聘专家，负责教授检查技巧。

Graduated from the Medical College Affiliated to Shanghai Jiao Tong University, in his 25 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.

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）, 67 times FDA 21 CFR 820 on site QSIT experience and 6 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 2018, Mr. Yu has consulted 67FDA level II inspections, among them, 53 times were accomplished on NAI result with Zero defect, cases cover but not limited to Medtronic, Terumo, Acon, Andon, Neusoft, BD diagnostic, smith nephew, Zimmer-Biomet, JnJ - Depuy etc.，specifically in 2017, Mr Yu assisted a Class III Device PMA preapproval inspection in US with NAI result with Zero defect.

Meanwhile， through China CFDA start the oversea inspection, from the end of 2015, Mr. Yu was involved the preparation of the upcoming oversea inspection by CFDA, so far 8 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 it’s 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
….

In 2017, Mr.Yu was appointed by CHINA FOOD AND DRUG ADMINISTRATION INSTITUTE OF EXECUTIVE DEVELOPMENT as the tutor for the CFDA oversea inspector to coach the inspection skill.

计利方先现为BSI 中国区医疗器械业务总监。计利方已经在 BSI 工作十五年，他在 BSI 担任过质量管理体系高级审核员、高级讲师、欧盟公告机构 CE 认证项目经理及产品专家等职务。计利方已经

为数百家医疗器械公司提供过过千次现场审核，技术文件评审和培训服务，培训课程包括 IRCA ISO13485 主任审核员课程，ISO14971 风险管理、 MDD 指令、临床评估、售后监督及警戒系统、技术文件评审、单一审核方案 MDSAP 和欧盟新法规 MDR 等课程。

Lane JI is the Medical Devices Director of BSI China. Lane has been working for BSI for 15 years as QMS Leader auditor, Leader Tutor, Notified Body Scheme Manager and Product Specialist for CE marking etc different roles.
Lane JI has delivered thousands of auditing, technical file reviews and training courses for hundreds of medical companies, including IRCA ISO 13485 Lead auditor, ISO 14971 risk management, MDD directive, clinical evaluation, PMS & Vigilance, technical file, MDSAP and EU new MDR etc training courses.

俞晓立，主任医师，硕士研究生导师，博士后合作导师

从事临床工作二十五年，能开展先心病、瓣膜病、冠心病和大血管疾病的诊治，对重症心脏瓣膜病外科治疗经验丰富。从事科技创新与科技创业的实践与教学，开设了公选课“科技创新基础”、“医疗器械的使用与设计”。开展了免缝合大血管吻合器、系列消化道吻合器、微创引流器械和含药 CVC 等的研制。广东省知识产权局知识产权专家库专家。有授权的发明专利四项，授权的实用新型十项。

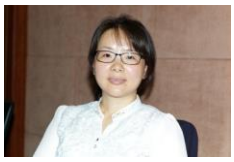
Bertrand BORDES， Global Market Manager

毕业于巴黎高科,高分子材料 博士.在研发方面拥有丰富的经验，职业生涯开始于罗地亚聚酰胺，然后进入罗地亚机硅；拥有六西格玛黑带和内部 ISO 审核员资质.从 2008 年到 2012 年，参与了国际汽车开发项目的工作，并获得了有机硅用于安全气囊和纺织涂层的创新专利。2012 年开始进入商务领域，担任 Elkem 有机硅医疗健康市场的全球市场经理；并致力于推广医疗级有机硅解决方案。
Graduated from Paris Institute of Technology; PhD in Polymer Science.Long experience in R&D, starting with Rhodia Polyamide then moving into Silicones;Six Sigma Black Belt and internal ISO auditor;From 2008 to 2012 patented innovative silicone formulations for airbag and textile coating and worked in International automotive development projects.Moved to business in 2012 and since then promoted Medical-grade Silicone Solutions with a Personal touch,as global market manager for the Healthcare market with Elkem Silicones

王成焘，教授，上海交通大学，生物医学制造与生命质量工程研究所学术带头人

Chengtao Wang, Professor, Shanghai Jiaotong University

博士生导师，中国机械工程学会荣誉理事，生物制造分会副理事长，上海生物医学工程学会荣誉理事，康复研究会副会长。近 30 年致力于工程学与医学相结合的交叉学科研究，研究领域包括：1.人体骨肌系统生物力学与生物摩擦学；2、临床数字技术，包括：虚拟手术、手术导航与机器人、系统集成与数字化手术室、医学 3D 打印技术； 3.骨外科植入物，包括人工关节、人工骨及其生命化技术等。曾主持国家自然科学基金 “中国力学虚拟人” 重点项目、亚洲人工关节重大国际合作项目及面上项目 15 项，获省部级科研成果奖 14 项，科研成果“个性化人工骨关节 CAD/CAM 技术与临床工程系统”获 2004 年国家科技进步奖二等奖。出版国家和地方科学专著基金资助著作 4 部，三部获部与国家级科学专著二、三等奖。拥有授权国家发明专利 30 项。



李春霞，医疗设备可靠性研究室主任，机械工业仪器仪表综合技术经济研究所（仪综所）

主要从事可靠性工程应用技术研究，医疗设备产业发展及应用技术研究。医疗设备产业共性技术服务平台可靠性研究室主任，IEC/TC65 AG2 测控系统及设备可靠性工作组专家。医疗装备首台套保险与进口免税项目评审专家；中国医疗保健国际交流促进会临床医学与健康产业分会常务委员；《中国医学装备》杂志编委。主要成果有《国产医疗设备行业现状及推进自主产品发展应用报告》、《我国高端医疗设备行业发展现状分析与对策研究》、《医用手术机器人研究报告》、《临床工程技术评估与评价》、《医疗器械技术前沿》等。

叶菁，资深科学家和业务拓展总监，ITL 集团

Jane Ye, Senior Scientist and Business development, ITL Group

叶女士拥有多年医疗器械设计和商业化生产的经验，在 ITL 集团上海分公司 IES China 近 10 年的时间参与了多项产品的设计，研发到生产制造项目，同时还负责海外市场项目沟通工作。

Ms. Ye has the long-term experience in Medical device design & development and commercialized production. With ten years working in ITL China, she participates in many design & development and manufacture projects, meanwhile, she’s also in charge of the overseas market project communication.

王建良 ， 研发总监，巨翊科技（上海）有限公司

Aric Wang, R&D Director Joymed Technology (Shanghai) Co., Ltd

20 年研发经验，多年医疗器械研发服务经验，曾帮助众多国内外客户成功研发多款医疗器械。专注于医疗器械研发流程改进，缩短研发周期，提高研发质量。致力于为客户提供优良的研发服务。

over 20 years R&D experience. Specialized in medical device development for many years, and successfully developed many medical devices for international and domestic customers. Focused on improving the development process of medical device to shorten the development cycle and deliver better design quality. Strive to provide the best design service to the customer.

张小农，博士学位，现为上海交通大学材料科学与工程学院博士生导师

研究方向为生物医用金属材料与器械。先后主持国家科技部重点研发专项子课题、国家 863 高技术计划、国家自然科学基金和上海市科技发展基金等课题 30 多项，参编著作 3 部，发表学术论文 150 多篇，获得国家自然科学二等奖、上海市科技进步一等奖和二等奖。

自 2003 年起开始生物医用可降解吸收镁金属材料与器械的探索研究，对可降解镁合金体系设计、材料制备、力学性能、降解性能以及表面功能涂层改性等进行了系统的基础研究工作。所开发的基于营养元素的镁锌系可降解吸收生物材料应用于植入医疗器械的相关成果建立苏州奥芮济医疗科技有限公司，进行产品转化医学研究，部分植入医疗器械即将正式开展临床人体试验。在此领域已发表 SCI 索引论文 50 多篇、他引 1500 余次。与医学研究人员密切合作，主持或参与国家自然科学基金等课题经费超过千万元，已获得授权发明和实用新型专利 20 余项，培养了 10 多名博士和硕士研究生，“中国科学报”等媒体多次报道相关研究进展。

秦蕾，秘书长，包装专委会

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.

John P. Merritt, 业务开发总监（医疗/医药/日化）, 莫迪维克（上海）贸易有限公司
John P. Merritt,Business Development Director MCP
John P. Merritt 拥有丰富的医疗产品经验和专业的学术知识，曾先后就职于多家世界领先的医疗器械制造商、医疗包装材料供应商以及包装设备制造商。

John P. Merritt is one of a few individuals in the world with extensive international experience working for leading medical device manufacturers, as well as leading medical packaging material suppliers, and packaging machinery fabricators.

徐海英，技术副总经理，上海微创医疗器械（集团）有限公司
Haiying Xu, Vice-general manager of Tech, Moicroport
多年从事微生物实验室管理和环氧乙烷、辐射灭菌过程确认，熟悉医疗器械生产过程的微生物控制，有丰富的环氧乙烷和辐射灭菌常规过程控制经验。
全国消毒技术与设备标准化技术委员会委员，主导制定了 “环氧乙烷灭菌新产品的追加和过程等效”、“环氧乙烷分包灭菌要求”等 标准，参与修订环氧乙烷灭菌过程确认国家标准。
Engaged in EO/EB sterilization Validation and the Microbiology lab management for nearly ten years.
Specialized in the microbiological controlling of medical device manufacturing and expertized in EO/EB routine process sterilization.
Leaded the draft of the standards of “Product adoption and process equivalence for ethylene oxide sterilization” and “sterilization requirements for subcontracting of Ethylene oxide”.. Also attended the revising of GB of ethylene oxide process validation.

宋翌勤, 副理事长,中国医疗器械行业协会医疗器械包装专业委员会
Jimmy Song, Deputy Chairman
奥克兰理工大学管理专业；工商管理学硕士；中国医疗器械行业协会医疗器械包装专业委员会副理事长；中国医疗器械行业协会医用高分子制品专业分会理事；上海医疗器械行业协会理事；中国包装联合会包装印刷委员会理事；欧洲无菌屏障协会（SBA）会员;YY/T 0698 标准起草单位负责人；多项新型包装专利发明人；上海建中医疗器械包装股份有限公司董事、总经理；上海安帕克包装有限公司总经理；

程健翼 ，技术服务工程师,汉高
Jenny Cheng，Henkel
六年胶粘剂应用技术服务经验，医疗行业胶粘剂推荐，工艺优化及全面解决方案
Experience in adhesive application and technical customer service.

秦益民，博士，教授，MBA，泰山学者

1965 年 11 月生，浙江嘉善人。1986-1990 年在英国 Leeds 大学研究壳聚糖纤维的生产方法及改性工艺，获纺织化学博士学位。1990-1993 年在英国 Heriot-Watt 大学从事博士后研究工作。1993-1998 年在英国 Advanced Medical Solutions 公司从事海藻酸盐纤维与医用敷料的研究与开发工作，担任公司研发部经理。1998-2000 年在英国 Manchester Business School 攻读 MBA 学位，以优等生毕业。2000-2001 年在英国 SSL International 公司从事具有抗菌性能的含银海藻酸盐纤维与医用敷料的研究与开发工作。2002 年回国后在嘉兴学院任教。主持研究山东省泰山学者蓝色产业计划、国家工信部生物基纤维强基工程项目等多项科研项目。在国际国内核心刊物发表科研论文 150 余篇，获得 7 项美国专利及 10 余项中国专利授权。撰写的学术专著《功能性医用敷料》、《海藻酸》、《Medical Textile Materials》、《海藻酸盐医用敷料的临床应用》、《Bioactive Seaweeds for Food Applications》在 2007、2008、2016、2017、2018 年分别由中国纺织出版社、中国轻工业出版社、Elsevier、中国知识出版社、Academic Press 出版，编写的《化工设计简明双语教程》双语教材和科普读物《海藻的故事》2010 和 2016 年分别由中国轻工业出版社和知识出版社出版。被评为山东省蓝色产业计划创新团队领军人才-泰山学者，担任海藻活性物质国家重点实验室主任。

张贵 深圳市领先医疗服务有限公司实验室主任，临床医学检验专业先健科技(深圳)有限公司生物测试部经理
Gui Zhang, Director of Shenzhen Advanced Medical Services co. LTD

先后负责组建先健科技生物学评价实验室、动物实验室和微创介入导管室工作；在生物相容性评价和临床前动物实验研究工作经验丰富，熟悉的全球法规和质量管理体系，并善于应用到实际工作中。10 年以上三类植入高风险医疗器械生物学评价和临床前动物实验研究经验，临床前动物试验技巧娴熟。负责首个铁基全降解冠脉支架生物学评价和临床前安全性研究工作，并已经进入临床试验， 曾参与多项国家级、省市级科技项目，发表高水平专业学术论文数十篇，其中 Cytotoxicity and its test methodology for a bioabsorbable nitrided iron stent 已被 ISO 37137-2 大篇幅引用，成为可降解生物材料细胞毒性方法。参与国际权威心脏病专家 Patrick

Serruys 主编的 Bioresorbable scaffold: From basic concept to clinical applications 一书，负责铁基全降解冠脉支架章节的内容。

Gui Zhang, Clinical laboratory medicine major, manager of Test Department of Lifetech Scientific (shenzhen) co. LTD, established biological evaluation laboratory, animal laboratory and cath lab for intervention operation. with rich experiences in biological evaluation and preclinical animal studies of medical devices, familiar with the applications of international standards and regulations and quality management system of cardiovascular implants. engaged in biological evaluation and preclinical animal studies of Class III high risk medical devices for more than 10 years, has skilled animal interventional operations . Responsible for biological evaluation and preclinical animal studies of the first iron-based degradable coronary stent which had been got access to clinical studies. Took part in many national and provincial and municipal science and technology projects, and published dozens of high-level academic papers. One of the papers is Cytotoxicity and its test methodology for a bioabsorbable nitrided iron stent, which is quoted by international standard ISO 37137-2 as a recommended cytotoxicity test method for degradable materials. Responsible for the iron-based degradable coronary stent parts of the book Bioresorbable scaffold: From basic concept to clinical applications by Patrick Serruys who is a chief editor and an international leading cardiologist

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

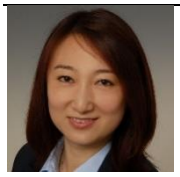
过去 17 年，孙德岚先生作为中国和欧洲的公司战略专家，在生命科学、医疗器械和健康服务领域领导并制定了多个切实可行的公司增长战略。孙先生对政府、政府企业、世界顶级企业、创业者和金融投资者的广泛领域客户提供战略决策服务。

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。
孙先生拥有剑桥大学制造工程学工程学硕士学位。
During the last 17 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.

Stephen holds a Master of Engineering in Manufacturing Engineering from the University of Cambridge.

Albrecht Poth，博士，Knoell
Dr. Albrecht Poth
Albrecht Poth 博士是医疗器械的高级毒理学家和业务发展主管，专注于医疗设备的全球注册和认证，并负责与客户的合作沟通。
他在医疗器械领域拥有超过 25 年的经验， 并曾担任 ISO 技术委员会 194（医疗器械临床前和临床评估）主席职位 10 多年。他目前担任的德国国家镜像委员会 ISO TC 194 ISO 主席，并从事专家工作组 TC 194 主席的工作。他积极从事于与多个合同研究组织的医疗器械测试的技术支持，科学支持和综合管理咨询工作。
Dr. Albrecht Poth is Senior Toxicologist and head of business development for medical devices. He is responsible for customer collaborations focusing on the global registration and certification of medical devices.
He has over 25 years' experience in the field of medical devices. He served for over 10 years as chairman of the ISO technical committee 194 (Pre-clinical and clinical evaluation of medical devices) and he is currently chairman of the German national mirror committee to ISO TC 194 and acting chairman of an expert working group within ISO TC 194. His functional experience includes technical, scientific and general management at several different contract research organizations active in the field of medical device testing and consulting.



周白雪,博士,Knoell
Dr. Baixue Zhou
周白雪博士 德国亚琛工业大学自然科学博士，亚琛应用科技大学生物医学工程硕士学士。现任职于德国 Dr. Knoell 咨询有限公司，从事医疗设备法规事务的相关工作，针对于医疗产品在欧洲和亚洲市场的认证为医疗产品制造商提供相关咨询，以及解决在医疗产品认证中所遇到的问题。她持有由德国认证机构 TÜV 所颁发的“国际医疗产品法规事务经理”和“医疗产品检查报告专家”认证证书，以及由德国认证机构 MEDCERT 所颁发的参加“欧洲新法规（MDR）”的讨论的证书。她可以提供在法规事务监管方面（欧洲法规 MDD，MDR）的专业支持，其中包括医疗产品设计的合规事务，医疗产品的检验报告，以及与认证机构的沟通。

Dr. Baixue Zhou was born in China, educated and works in Germany. She holds a Ph.D. with the major on Cardiology in Natural Sciences from Rheinisch-Westfälische Technische Hochschule Aachen (RWTH Aachen University), as well as a B. S. and a M. S. degree in Biomedical Engineering from the Aachen University of Applied Sciences in Germany.
She works at Dr. Knoell Consult GmbH in Germany on Regulatory Affairs for Medical Devices in European and Asian Market (Europe CE-marking and China CFDA approval). She holes a certificate of Manager Regulatory Affairs Medical Devices International and a certificate of Expert Technical Documentation Medical Devices provided by TÜV, as well as a participation certificate relating to MDR provided by MEDCERT. Her functional experience includes professional support on regulatory compliance in accordance with MDD and MDR, including regulatory support on product design development, technical documentation and communicating with Notified Bodies.

Lacey Chessor，Knoell
Lacey Chessor 是专注于美国医疗器械注册法规的监管专家和组长。她和她的团队为全球的医疗设备公司提供对美国市场监管要求的技术支持。
她在医疗器械领域拥有超过 10 年的经验，其中包括 5 年以上美国食品和药物管理局（FDA）的消费者安全官员。她还担任过二级和三级医疗器械公司的合规总监。她在产品上市前通知（510（k））和批准（PMA）方面，以及在以根据 FDA 规定建立和实施质量体系方面有丰富的经验。她持有法规事务专业协会（RAPS）所颁发的法规事务认证证书（RAC）。她可以提供在监管和质量方面的支持，其中包括与 FDA 沟通，提交上市前通知（510（k）），上市前批准（PMA），建立符合 21 CFR 第 820 部分的质量体系，并提供检查/审查协助。
Lacey Chessor is regulatory expert and group leader focusing on the U.S regulations for medical devices. She and her team provide support to medical device companies worldwide in understanding the regulatory requirements of the U.S. market.
She has over 10 years’ experience in the field of medical devices, including 5+ years as a Consumer Safety Officer for the U.S. Food & Drug Administration (FDA). She also has held the role as Director of Compliance for class II and class III medical device

companies. She has experience in premarket notifications and approvals, as well as a direct focus in establishing and implementing quality systems according to the FDA regulations. Lacey holds a Regulatory Affairs Certification (RAC) provided by the Regulatory Affairs Professional Society (RAPS). Her functional experience includes regulatory and quality support; including communicating with FDA, submitting premarket notifications (510(k)s), premarket approvals (PMAs), establishing quality systems in compliance with 21 CFR Part 820, and providing inspectional assistance.

Bill Harrison,安全评估中心副总裁,药明康德

PhD, Bill Harrison, VP, Safety assessment center

Bill 在 CRO 行业有 30 多年的工作经验。在加入药明康德之前，他是 VIDA Sciences 的创始人和首席执行官，VIDA Sciences 是一家专注于服务 CROs 的咨询公司，专注于提高性能。在此之前，Bill 是 MPI Research 的总裁兼首席运营官，MPI 是世界上最大的临床前 CROs 之一，他带领公司经历了一段相当长的成长时期。在加入 MPI 研究之前，他是 Pharmaco-LSR(现在是 Envigo 的一部分)的监管事务和运营总监。他是美国质量保证协会(SQA)的前主席。Bill 曾为许多公司和组织担任董事会成员，目前是美国生命科学创新委员会和 INSTEM 顾问委员会的董事。

Bill has over 30 years' experience in the Contract Research Organization (CRO) industry.Prior to joining WuXi AppTec, he was the founder and CEO of VIDA Sciences, a consulting company dedicated to serving CROs, focusing on performance improvement.Before then, Bill was President and COO of MPI Research, one of the largest preclinical CROs in the world, and led the company through a substantial period of growth.Prior to joining MPI Research, he was Director of Regulatory Affairs and
Operations at Pharmaco-LSR, now a part of Envigo. He is a former President of theU.S. Society of Quality Assurance (SQA).Bill has served on the Board for numerous companies and organizations and currently serves on the Board for the American Life Sciences Innovation Council and the INSTEM Advisory Board.

Mark A. Cabonce, M.S., DABT，法规和技术部门总监，药明康德

Director of Technical & Regulatory

Cabonce 先生在药明康德担任技术和法规部门总监，专注于医疗器械和组合产品。在加入药明康德之前，他是孟山都管理公司(Monsanto management)的毒理学研究监督员，负责在体内和体外进行急性毒理学研究，评估 GHS 分类和标签的配方档案，编写风险评估文件以支持国际产品注册。作为第七波实验室(切斯特菲尔德，密苏里州)的顾问和研究主任，他在现行的 EPA、FDA 和 OECD 指导方

针下，管理了广泛的药物代谢动力学和临床前安全评估研究。他拥有圣路易斯大学生物学硕士学位，自 2005 年以来一直拥有美国毒理学委员会资格。

Mr. Cabonce serves as a Director of Technical and Regulatory at WuXi AppTec with a focus on medical devices and combination products. Before joining WuXi AppTec, he served as a toxicology study monitor at Monsanto managing regulated in vivo and in vitro acute toxicology studies, assessing formulation dossiers for GHS classification and labeling, and preparing risk assessment documents in support of international product registrations. As a consultant and study director at Seventh Wave Laboratories (Chesterfield, MO), he managed pharmacokinetic and preclinical safety evaluation studies for a broad range of pharmaceutical and agrichemical clients under prevailing EPA, FDA, and OECD guidelines. He holds a M.Sc. degree in Biology from St. Louis University, and has been a Diplomat of the American Board of Toxicology since 2005.

Sandi Schaible，分析化学部门总监，药明康德
Director, Analytical Chemistry
Schaible 女士拥有超过 25 年的经验，负责药明康德位于明尼苏达州圣保罗的分析化学部门的监督和指导。她所管理分析化学部门主要负责提供自定义化学测试服务，包括可提取/过滤材料、材料特性描述和目标分析测试、方法开发、方法验证以及标准化测试(包括补充测试)。Schaible 女士从明尼苏达州的威诺娜州立大学得化学学士学位，并在制药、医疗器械、环境和研发行业工作，包括在 GLP、GMP、FDA 和 ISO 管理的实验室 15 年以上的分析经验。Schaible 女士提供技术指导和测试程序设计，被指定为国际和美国 TC194， 她同时也是 ISO10993 技术委员会委员。

With over 25 years' experience, Ms. Schaible is responsible for oversight and direction of WuXi AppTec's Analytical Chemistry department in St Paul, Minnesota. The analytical staff she manages is responsible for providing custom chemistry testing services including extractables/leachables, materials characterization and target analysis testing, method development, method validation as well as standardized testing including compendial testing. Ms. Schaible received her Bachelors of Science in Chemistry from Winona State University, and has experience working in the pharmaceutical, medical device, environmental and R&D industries, including over 15 years of analytical experience in GLP, GMP, FDA and ISO regulated laboratories. Ms. Schaible provides technical guidance and testing program design, and is an international and U.S. delegate for TC 194, the technical committee for ISO 10993.

Sean Colwell, B.A.技术总监,药明康德，药明康德
Technical Director

肖恩•科尔韦尔是一名微生物学家，在医疗器械和制药行业拥有 25 年经验。在 CRO 公司和注射用药物的制造企业，他领导过微生物和质量保证团队。Sean 于 2016 年加入药明康德担任技术总监，目前带领微生物检测及灭菌验证服务。肖恩在俄亥俄州的迈阿密大学获得了微生物学学士学位，并在俄亥俄医学院攻读研究生。

Sean Colwell is a microbiologist with 25 years of experience in the medical device and pharmaceutical industries. He has lead microbiology and quality assurance teams within contract testing
and parenteral manufacturing organizations. Sean joined WuXi AppTec in 2016 as Technical Director and currently leads a team performing microbiology testing and sterilization validation services. Sean received his Bachelor’s degree in Microbiology from Miami University in Oxford, Ohio and pursued post-graduate studies at the Medical College of Ohio.