亲爱的 CQAF 成员，

2020 即将过去，2021 悄然来临！CQAF 也迎来了新一届任期（2021-2023）的核心团队！

借此机会，我们很高兴地宣布，徐晓刚当选为主席，并热烈欢迎张萍加入 CQAF 核心团队[1]。此外，陈华和张兰晶将作为法人和秘书继续支持 CQAF。新一届任期自 2021 年 1 月 1 日起生效。请参考以下核心团队的介绍。

非常感谢 CQAF 小伙伴 2020 一路的陪伴，祝大家 2021 年新年快乐!

CQAF 核心团队

Dear CQAF members,

2020 is just right in the corner，and 2021 is coming quietly! CQAF is also welcoming a new term (2021-2023) of the core team!

Taking this opportunity, we are pleased to announce that Sean (Xiaogang) XU is elected as the Chairman and warmly welcome Sally(Ping) ZHANG to the CQAF core team [1]. In addition, Hannah CHEN and Lanjing Zhang will continuously support CQAF as the Legal representative and General Secretary. The new term will come to effective since 1 January 2021. Please refer to core team members' biography as below.

We much appreciate your constant companion in 2020, and wish you a very happy New Year of 2021!

CQAF Core Team

徐晓刚 Sean (Xiaogang) XU, Chairperson, Beijing

徐晓刚毕业于中国药科大学拥有临床药学本科学历，同时在中国科学院研究生院完成了项目管理研究生课程班的学习。

徐晓刚目前就职于 Zigzag Associates Ltd.（一家为全球制药/生物公司提供 GxP 质量保证服务的供应商），担任亚太区质量保证（QA）服务副总监。自 2003 年以来，在为国内/国际制药公司和 CRO 公司工作的过程中，他在制药和医疗器械研发领域积累了丰富的经验，

[1] According to the sequence of the surname

尤其是在临床试验运营、人员管理、项目管理和质量保证方面。自 2010 年以来，他在 GCP 稽查方面积累了较多的经验，包括在亚太地区完成各种类型的 GCP 稽查，比如对研究中心、供应商、系统、试验文件、子公司和公司内部部门的稽查工作。积极主动，且具有良好的管理技能，他成功领导了全球临床试验在亚太地区的执行以及本地临床试验项目的开展，负责内容从试验启动到关闭，项目涉及到多个不同的治疗领域。徐晓刚在 2012 年加入 CQAF，并积极参与和支持 CQAF 发起的活动和培训项目。在社会活动方面，他目前担任国家药品监督管理局高级研修学院的兼职讲师以及亦弘商学院的课程教授。

Sean holds a bachelor degree in Clinical Pharmacy from China Pharmaceutical University and a Certificate of Completion of Master Courses in Project Management from Graduate University of Chinese Academy of Science. Sean is currently working for Zigzag Associates Ltd., a global GxP QA Services Provider, as Associate Director of QA Services for Asia Pacific. He is a highly experienced professional with significant operational, project/people management and QA experience within the pharmaceutical and medical device industries since year 2003, for both MNCs and CROs. Expertise in GCP auditing across a wide range of audit types including clinical investigator site, vendors, systems, documents, affiliates and internal departments in Asia Pacific area since 2010. Proactive and with excellent managerial skills, he has led both global clinical trials and those local to the Asia Pacific region, from start-up to close-out, and in a wide range of therapeutic areas. Sean joined CQAF in year 2012 and has been actively participating in and supporting CQAF initiatives and training programs. In the area of social activities, he currently serves as a part-time lecturer at the IED of NMPA and course professor for Yeehong Business School.

蒋燕敏 Amy (Yanmin) JIANG, Core member, Shanghai

具有超过 20 年的制药行业经验。2019 年 11 月加入和铂医药，负责 GxP 质量管理体系的建设和维护。之前，一直服务于赛诺菲公司中国研发中心，曾负责协调中国研发中心本地日常运营和全球大型活动，保持中国研发中心内外部的互动；曾负责中国研发中心 GxP 质量管理系统和运营七年；并曾从事药物临床研究和运营十年，成功领导过肿瘤、心血管等不同治疗领域的数个大型临床试验。

加入制药行业前于上海一家三甲医院有五年的肿瘤医生任职经历。毕业于上海交通大学医学院（原上海第二医科大学）临床医学专业。

此外，热心于推动中国临床试验的发展。公司内部负责协调面向医院的临床研究相关培训，对外，是中国质量保证论坛（CQAF）的核心团队成员；担任国家药品监督管理局高级研修学院和亦弘商学院的课程教授。

Amy has more than 20 years' experience in pharmaceutical industry. Amy joined in Harbour BioMed responsible for GxP Quality Management in Nov. 2019. Before that, Amy was serving in

[1] According to the sequence of the surname

Sanofi as China R&D Site Head responsible for coordinating local operations and global activities and interacting internally and externally; was responsible for GxP quality management system and operations in China R&D for seven years; and ten years in drug clinical research and operations, has ever successfully led several large-scale clinical trials in different therapeutic areas such as oncology and cardiovascular.

Prior to joining in the pharmaceutical industry, Amy has worked as an oncologist in a Shanghai Tier-3 hospital for 5 years. Graduated from Medical School of Shanghai Jiaotong University (formerly Shanghai Second Medical University), majoring in clinical medicine.

In addition, Amy is keen to promote the development of clinical trials in China. In the company she is responsible for coordinating clinical research related training for hospitals. Externally, she has worked as a core team member in China Quality Assurance Forum (CQAF) and served as a course professor at the IED of NMPA and Yeehong Business School.

刘海涛 Heidi(Haitao) LIU, Core Member, Shanghai

刘海涛，医学背景，以全科医生开始了她的职业生涯。2004 年，她获得国际公共卫生硕士学位后，便转入临床试验领域。其中包括担任世卫组织 TDR 项目的监查员和稽查员、亚太地区伦理审查委员会论坛（FERCAP）的医务官员，负责上海华山医院临床研究机构的培训和合规工作，北京大学伦理委员会办公室主任。自 2012 年起在药企担任 GCP 合规和质量保证工作，于 2020 年加入瑞士卫森医药咨询公司，作为质量管理&质量保证咨询顾问。在 QA 的日常工作中有很多“视情况而定”，她相信合理和意义是正当性的必要条件，而合规性应以普遍公认的道德原则为基础。

HAITAO (HEIDI) LIU, medical background and started her career as a general physician. Once she completed Master Degree in International Public Health in 2004, she moved to the field of clinical trials. This has included experience as a contract monitor and auditor for WHO TDR’s projects, Medical Officer of Forum of Ethical Review Committees in Asian & Western Pacific Region (FERCAP), Training and Compliance Officer in the Clinical Research Institute of Shanghai Huashan Hospital, the Office Director for Peking University Institutional Review Board. Since 2012, she has been working as GCP Compliance and Quality Assurance professional in industry. With a lot of “it depends” in QA’s daily work, she believes reasons and meanings are essential for justification, and compliance should be anchored on universal ethical principles.

[1] According to the sequence of the surname

刘清月 Cathy (Qingyue) LIU, Core Member, Shanghai

具有超过 20 年的制药行业经验，先后服务于三家国际制药公司从事临床试验运营，质量与培训和质量保证的管理工作。稽查经验涉及 GCP，GCLP 和 GVP 领域，稽查的区域主要涉及亚太区各国以及欧洲和美国。
现任罗氏全球药品开发质量保证部亚太区负责人和全球质量策略专家，主要负责罗氏全球药品开发 GCP 质量策略的制定以及通过与各部门的合作确保 GCP 质量策略在药品研发流程的实现，同时对亚太区提供质量方面的支持。
此外，积极参与和推动中国临床试验的质量。从中国质量论坛成立之初加入，自 2016 年以来担任 CQAF 核心团队成员和上界中国质量论坛主席（2018-2020）。

Cathy currently holds the position of Site Head for Roche Pharma Development Quality (PDQ) Asia Pacific & Quality Strategy Lead. Cathy's primary responsibilities are to assure the realization of Roche Pharma Quality Strategies in the clinical development process space and provide quality support to the APAC region.
Have been working in pharmaceutical industry for more than 20 years, Cathy had increased responsibilities and management experience at MNCs, where she was mainly responsible for Clinical Operations, Quality Management and Global Quality Assurance of the GxP audit programs in the GCP/GVP/GCLP fields from 2009 to 2016.
Joined CQAF from the foundation, Cathy has served as a member of the CQAF core team since 2016 and chairperson for 2018-2020.

Ellyne SETIAWAN , Core Member, Shanghai

Ellyne 来自新加坡，自 1998 年以来一直专注于医药研发领域；在进入质量管理领域之前，她大部分时间都在亚洲、中东和欧洲的临床运营部门担任各种职务。Ellyne 现任勃林格殷格翰大中华区医学部质量负责人，她与高度敬业、充满活力的质量专家团队一起，在组织内推动质量文化、合规性、改进、知识和学习。Ellyne 于 2015 年初加入 CQAF，此后一直积极推动和支持 CQAF 的多项重点工作。她秉持公平、透明的个人价值观，以及开放沟通和团队合作的工作原则。

Ellyne is from Singapore and works in the clinical research industry since 1998; spending most of her time in clinical operations across Asia, MENA and Europe holding various positions before moving into quality management. Currently, she is leading the Quality Medicine function in

[1] According to the sequence of the surname

Boehringer Ingelheim's Chinese Markets. Together with a team of highly dedicated and dynamic quality professionals, they drive quality culture, compliance, improvements, knowledge and learnings with passion within the organization. Ellyne joined CQAF at the start of Y2015 and has since been actively contributing to and supporting a number of CQAF priorities. She is guided by a set of personal values of being fair and transparent as well as the working principles of open communication and team work.

沈一峰 博士 Dr. Yifeng SHEN, Core Member, Shanghai

第二军医大学本科（1996），复旦大学上海医学院硕士（2002）、博士（2011）。美国临床研究专业协会（ACRP）认证研究医生（CPI®，2009~）。Rutgers New Jersey Medical School 高级访问学者（2015-2016）。

上海市精神卫生中心主任医师，机构办公室主任、质量保证负责人和伦理委员。国家“重大新药创制”科技重大专项精神药物 GCP 平台副组长（2008~2020）。国家药监局药品审评专家和 GCP 检查员。

Dr. SHEN, Yifeng received B.S.Med. (1996) in clinical medicine from Second Military Medical University, M.S.Med. (2002) and M.D. & Ph.D. (2011) in psychiatry from Fudan University Shanghai Medical School. Since 2009, he has become a CPI® of ACRP. He was a senior visiting scholar of Rutgers New Jersey Medical School. (2015-2016)

Yifeng is now a chief psychiatrist, director of GCP office, QA team leader and IRB member of Shanghai Mental Health Center. Also he is minor head of the National Science and Technology Major Project (NMP) for IND in psychiatry (2008-2020). He is a CDE reviewer expert and a GCP inspector of NMPA.

于桂琴 Guiqin YU, Core Member, Beijing

1998 年 7 月毕业于北京医科大学，并获得妇产科硕士学位。

目前担任拜耳医药保健有限公司临床试验稽查亚太区执行总监。负责亚太区（包括日本）人员管理，具有丰富的在亚太区及全球质量保证稽查经验，包括试验中心稽查、供应商稽查、文件稽查、流程稽查、部门内审、GLP 稽查等。

具有 19 年的临床试验经验，11 年质量保证的工作经验。

[1] According to the sequence of the surname

GUIQIN YU was graduated from the Beijing Medical University in Jul 1998 with master degree of Gynecology & Obstetrics.

Guiqin currently holds the position of Executive Director, head GCP Study Audit Management Asia Pacific, Research & Development Quality, at Bayer Healthcare, with managerial responsibility for the Senior/Global Clinical Auditors, and 2nd level line managers located in Asia Pacific including Japan, and has extensive clinical quality assurance auditing experiences covering mainly for GCP audits such as investigator site, supplier and document audits, but also has experience of GLP audit, process audit and medical affiliate audits in Asia Pacific and at global level.

Guiqin has 11 years working experience in the area of quality assurance and 19 years in Clinical Research area.

周立萍 Liping ZHOU, Core Member, Beijing

周立萍现任默沙东研发(MRL) 亚太区质量保证部高级总监，拥有 21 年医药行业从业经历: 11 年医药研发 QA 专业领域国内、外独立稽查、国际药监核查管理经验，并致力于亚太 QA 团队的建立和管理，质量文化和临床质量管理体系的推动；5 年临床研发运营，含监查、培训和人员管理；进入临床研发前，从事近 2 年临床工作和 3 年医药销售。先后就职于诺华制药，拜耳医药，默沙东等跨国药企研发机构。

中国质量保证论坛（CQAF）第三任主席和现任核心成员。毕业院校：北京医科大学（现北京大学医学部）

LIPING ZHOU is currently working as Senior Director and QA Head for MSD Research Laboratories (MRL), Asia Pacific. Liping have 21 years' working experience in the industry: over 11 years in Pharma R&D Quality Assurance, with increased scope and responsibilities in the area of GxP audits and inspections worldwide, in addition to building Asia Pacific QA team in MRL and promoting Quality standard and culture in the industry; 5 years in clinical operation as site monitor, GCP training manager and line manager. Worked for MNC, including Novartis, Bayer Healthcare and MSD. Liping is a core member in China QA Forum (CQAF) and acted as the chairperson for the third term. Liping graduated from Beijing Medical University (current named as Peking University Health Science Center.

[1] According to the sequence of the surname

张萍 Sally (Ping) ZHANG, Core Member, Shanghai

Sally 在 CQAF 成立之初即成为一员，2010 年她的 QA 职业生涯在辉瑞全球质量保证部门开始。她之前的工作经历还包括在阿斯利康中国研究开发部从事临床运营工作。辉瑞之后，Sally 于 2018 年初加入领先的中国生物制药公司基石药业，作为质量管理副总裁全面领导公司临床质量管理体系以及质量管理策略的实施。
Sally 在加入制药行业前是一名耳鼻喉科医生，她毕业于四川大学华西医学中心，在中国和加拿大达尔豪斯大学联合培养硕士研究生项目中获得研究生学历。
从 2019 年开始，Sally 作为中国业界专家代表，在 ICH 全球专家组成员从事 ICH GCP R3 的全球变革工作。

Sally (Ping) ZHANG joined CQAF since foundation when she started her QA career. Her prior work experiences included clinical operations and quality assurance at AZ China R&D and Pfizer global QA respectively. In recent 3 years, she works in China leading biotech CStone as VP of QA, where she takes overall leadership of clinical QMS, organizational quality management strategy and implementation.
Sally was an ENT doctor before joining industry. She graduated from Sichuan University Huaxi medical center with Master's degree, under a partnering graduate program with Dalhousie University of Canada.
Sally has also been working in ICH Global Expert Working Group (EWG), for ICH GCP R3 renovation since 2019.

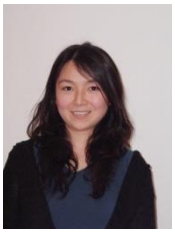
陈华 Hannah(Hua) CHEN, Legal Representative, Beijing

陈华于 2019 年 2 月成立了自己的咨询公司开始做独立咨询顾问。陈华有超过 20 年在跨国制药公司工作的经验 （葛兰素史克 1997.5～2012.9；强生 2012.9～2019.1），从事过的专业领域包括：临床试验监查，试验管理，方案设计和试验总结报告；GCP 稽查包括研究中心，当地公司和供应商稽查；临床试验实验室稽查和药物警戒系统的稽查；临床试验质量管理体系 (cQMS）的培训、搭建和改进；基于风险的监查(RBM)等专题培训。
陈华于 2010 年 5 月创建了中国质量保证论坛 (CQAF)，旨在推动在 GXP 领域的质量标准。陈华在促进 CQAF 与国内外行业协会的合作中担任重要角色，如与 RQA，RDPAC 和 DIA 的合作。

HANNAH is the founder of Hannah and Associates (Consulting company), she has more than 20

[1] According to the sequence of the surname

years experience in Pharm Industry including GSK and JNJ. She has experience in: clinical operations, project management, protocol and CSR development; She conducted GCP audit including investigator site, local operating company and external service provider; clinical laboratory and PV audits. She provided training in auditing, cQMS set up and RBM. Hannah is the originator and founded the CQAF in May 2010 and chaired forum from May 2010 to May 2012. She plays important role in external engagement including RQA, RDPAC and DIA.



张兰晶 Lanjing ZHANG, General Secretary, Shanghai

张兰晶，苏州大学生理学硕士，自 2011 年起担任罗氏制药的医疗事务合规与卓越经理，负责支持中国本土 GCP 和 GVP 活动中质量管理体系的持续改进。在此之前，她曾在 Covance 和中信国健等国内制药公司的临床研究和市场医学部门工作 5 年，并作为全科医生 5 年。张兰晶于 2012 年 2 月加入中国质量保证论坛（CQAF），担任秘书，负责协助 CQAF 主席和核心团队工作，确保 CQAF 日常工作顺利进行。

LANJING holds a Master's degree in Physiology, Soochow University, and currently is Medical Affairs Compliance & Excellence Manager in Roche Pharma., supporting continuous improvement in local Quality Management System in GCP and GVP activities in China since 2011. Before that, she works in clinical research and marketing medical department in Covance and CP-GJ pharmaceutical company for 5 years, and as general practitioner for 5 years.
LANJING join in CQAF as General Secretary since Feb 2012, with the responsibility to support CQAF Chairperson and Core Team to ensure the CQAF daily work run smoothly.

[1] According to the sequence of the surname