

Topic Preview: From research to Development to Commercial- a Success Story on How to Scale up Together

演讲预告：从实验室到产业化——在合作中成长

14:35-15:05, 20th June, 2017 Hall E2 M17 Meeting Room, SNIEC, Shanghai
14:35-15:05, 2017年6月20日, E2馆M17会议室, 上海新国际博览中心



Wendy Xia
Director, Commercial Supplies,
Agius Pharmaceuticals

Wendy is a seasoned supply chain professional with 22 years of combined experience in Pharmaceutical R&D.

After completing her graduate work at Buffalo State College, Wendy started her career as a research chemist at Cornell University Research Park in Ithaca, New York. She then moved on to spend 17 years in pharmaceutical development, International Quality and Global Clinical Supplies at Schering Plough, Merck and Novartis.

In 2014, Wendy joined Agios, a biopharmaceutical company in Cambridge, Massachusetts. In 2 years, Wendy established a clinical supply chain group equipped with resources, processes, procedures and necessary IT tools including a fully validated part 11 compliance inventory system.

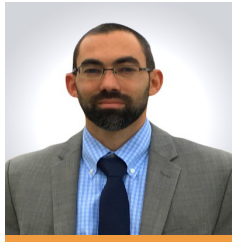
In 2016, as Agios started transition from a research to commercial organization, Wendy took on the responsibility to lead and establish a commercial supply chain group. Getting ready to launch Agios's first commercial drug in 2018 will complete the end to end supply chain experience, from research to patients.

Wendy Xia
Agius商业供应总监

Wendy在医药研发领域拥有22年丰富经验，先后在先灵葆雅（Schering Plough）、默克（Merck）和诺华（Novartis）从事药物开发、国际质量和全球临床供应等工作。

2014年，Wendy加入Agius，并在2年内建立起一支强大的临床供应链团队，配备了齐全的资源、程序以及信息技术工具，其中包括一套完全合规（符合《联邦法规21章》第11款要求）的库存系统。

2016年，Wendy的职责从临床研发供应转向商业化供应，带领成立了Agius商业化供应链团队，为Agius在2018年即将上市的首个商业药物的终端供应做好准备。



Christopher M DiNardo MBA
Manager of Procurement,
Agius Pharmaceuticals

Christopher is a seasoned Procurement professional with 10 years of combined experience in pharmaceutical strategic sourcing.

In 2016, Chris joined Agios, a biopharmaceutical company in Cambridge, Massachusetts, where he leads the procurement function for the Technical Operation group and is a team member of Agios' first commercial drug candidate supply launch. Chris drives sourcing efforts through the supply chain. Throughout this process, Chris is an expert at managing and implementing supplier agreements with contract manufacturers to support the commercialization of pipeline products. Chris is skilled at fostering the supplier relationship in order to make a more open, working dialogue between CMO and Agios. In addition, he is focused on achieving savings targets by partnering with internal stakeholders and instituting process improvements.

Christopher M DiNardo MBA
Agius采购经理

Christopher在制药战略采购领域拥有10年丰富经验，先后服务于精鼎医药（PAREXEL）、DUSA（现为Sun Pharma）以及Cubist（已被默克收购），负责现场生产采购、API及关键中间体采购等工作。

2016年，Chris加入Agius，带领技术运营采购团队，并成为Agius首个商业候选药物供应团队的关键成员。Chris主要负责供应链中的供应商选择，管理并落实与生产制造商之间的供应协议签订，以此支持产品的商业化生产。Chris在供应商关系维护方面非常专业，促进制造商与Agius之间更加开放、有效的沟通。此外，他还通过与内部利益相关方合作以达到成本节约目标，并实行流程改进。



Dr. Haijun Dong
Chief Executive Officer,
PharmaBlock Sciences (Nanjing), Inc.

Dr. Haijun Dong, CEO of PharmaBlock, has strong background and formal training in both technical field and business management. Before joining PharmaBlock, he worked as COO of Lilly China R&D Center, Head of DMPK and Drug Safety at Roche R&D (China), Senior Principal Scientist at Roche Nutley, as well as Managing Director of DIA China. Ph.D. in chemistry and pharmaceutical sciences from the University of Washington of the US and MBA from China Europe International Business School.

董海军博士
南京药石科技股份有限公司首席执行官

董海军博士现任南京药石科技股份有限公司首席执行官，他在医药研发领域拥有丰富的科研及管理经验，曾任职于罗氏美国/中国研发中心，担任礼来中国研发首席运营官，DIA中国区董事总经理等管理职位。董海军博士拥有美国华盛顿大学博士学位，中欧国际商学院工商管理硕士学位。



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What topics you will share with us on 2017 CPhI CRO & CMO Forum?

Wendy: We plan to present the audience with a success story that showcases how Agios and PharmaBlock worked seamlessly in past 4 years and together supported an incredible development milestone- from first in human to NDA in less than 4 years. We will share the topic including but not limited to 1) selection criteria for commercial production suppliers (key and regulated starting material) 2) Why we chose to establish a commercial supply agreement

Haijun: From PharmaBlock's end, we have gained reputation for our outstanding capability in the design, synthesis, and supply of lab scale building block. While this time we would like to share with audience how we extend and prove our capabilities from lab-scale to manufacturing through the partnership.

How did Agios and PharmaBlock form the partnership from the beginning?

Wendy: Although the initial contact happened between two companies was rather random. It was the strong research capability from both sides contributed to a solid relationship. The development projects started at the very early stage of discovery, mostly on building blocks.

How the partnership helps both sides to grow?

Wendy: Agios and PharmaBlock are at pivotal times within their company's growth. By partnering with an emerging CMO, both companies are on the same path moving their respective company forward to a progressive future. As Agios target compound moves from discovery to development and now commercial stage. Both companies are fully aligned in terms of business goals and capabilities. We are ready for the challenges ahead.

Haijun: We have learned a lot from the partnership, which drives us to grow and take more challenges, in terms of technology development, operational standardization and even business model optimization etc. We are also grateful that Agios always shares with us their experiences and good practices as the company grows.

What are advantages to develop drug on both sides of Pacific Ocean? And what are challenges? How to manage these challenges?

Chris: Cross-ocean collaboration brings up many advantages including cost savings both on capital and expenditure, as well as easy access to large local talent pool. Agios outsourcing business model demands partnering with CMOs such as PharmaBlock.

Meanwhile, we are also facing some challenges as a sponsor working with a CMO across the globe. Giving the size of Agios, managing external CMOs with limited internal resources is a burden. We have to deal with additional contracts, purchase orders, invoices, ETC. Distance, time constraints and language barriers also bring us additional premium cost travel, export/imports and tax burdens, as well as risks during transit of high value shipments across the globe.

To overcome these challenges and mitigate risks, we find proactive planning, vigorous business justification and strengthen communication with transparency are vital to our success.

Haijun: It is our honor to be a part of life-saving drug R&D projects and witness every milestone they have achieved along the way. As an emerging CMO, we are encountering some challenges such as: policies/regulations gap between China and regulated market; higher request on QA, IP protection and IP strategy; and language/culture barriers. To tackle these challenges, we have implemented a local business development infrastructure close to our client's base, and built up a strong international team to maintain compliance.

您在2017 CPhI CRO & CMO论坛上将要分享的议题是什么?

Wendy: 我们将与大家分享Agios与PharmaBlock之间非常成功的一次合作, 在过去四年中, 我们通过紧密协作, 共同推动达成了这一不可思议的里程碑, 从第一次将候选药物用于人类临床试验到获批上市只用了不到四年时间。我们将会在会上谈一下商业化生产供应商的选择标准(关键规范化原材料), 以及我们为什么要签订商业化供应协议。

董海军: 从药石科技的角度来说, 我们从建立之初就已经在实验室级别分子砌块的设计、合成和供应方面获得了认可, 而这次我们将主要和大家分享作为供应商我们如何从合作中学习延伸并证明我们从实验室级别到商业化生产的能力。

Agios 和 PharmaBlock两家公司最初是如何建立合作关系的?

Wendy: 事实上两家公司是在很偶然的情况下开始接触的, 而在这个过程中, 我们双方扎实的研发实力进一步促成了紧密稳固的合作关系。我们从药物研发早期阶段就已经建立起合作, 以分子砌块需求为主。

这种合作关系是如何帮助双方共同成长的?

Wendy: Agios和PharmaBlock都处在快速成长的关键时期, 我们在合作中保持一致步伐, 推动公司进一步发展。随着Agios的目标化合物从早期研究到开发到目前的商业化阶段, 两家公司在商业目标和能力方面都十分匹配。我们已经为未来的挑战做好了准备。

董海军: 我们从合作中学习到了很多, 不断接受挑战, 从技术开发、规范化操作到商业模式优化, 推动我们更快地成长。我们也非常感谢Agios与我们分享公司在发展过程中一些好的经验和实践。

双方的跨洋合作给对方带来了哪些好处? 又有哪些挑战? 你们是如何应对这些挑战的?

Chris: 跨洋合作给我们带来了很多利好, 其中包括节省了资本和费用支出, 更容易接触到当地优秀人才。Agios的外包商业模式要求我们和优秀的CMO合作, PharmaBlock就是很好的例子。

而同时, 作为制药企业, Agios在与CMO进行跨国合作中也面临着一些挑战。基于Agios目前的规模, 我们需要通过非常有限的内部资源对外部CMO进行管理, 其中还包括额外的合同、订单、发票处理等。而距离、时差和语言等方面的差别也给Agios带来了额外得进出口费用和税务负担, 增加了跨国运输高价值物品的风险。

为了克服这些挑战, 我们认为需要更加积极的规划和有力的商业论证, 同时加强透明公开的沟通。

董海军: 我们非常高兴可以参与到这些改变人类命运的新药研发项目中去, 并一起见证这些重要的里程碑。作为一家比较年轻的CMO企业, 在跨国合作中我们的一些挑战主要在于: 法律法规方面的差异; 对于质量、IP保护方面更高的要求; 语言和文化差异。为了应对这些挑战, 我们已经在美国当地建立商业拓展基地, 并培养了一支精良的国际化团队来确保各项合作合规。

