Experience Sharing of application for DHA/PQP in WHO Prequalification Programme

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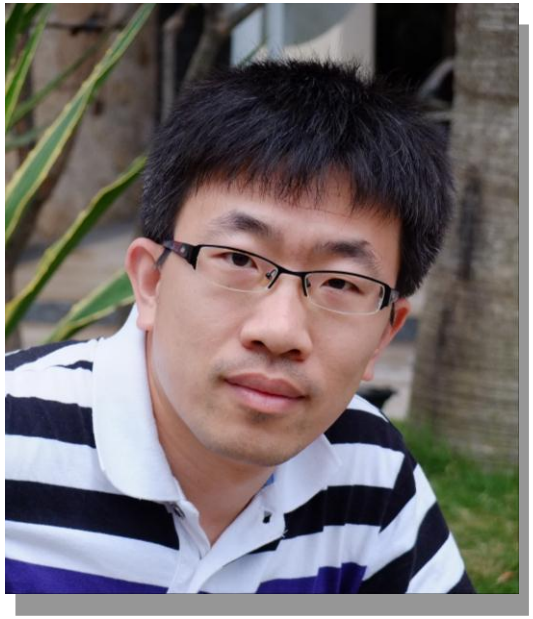
- Graduated form Shenyang Pharmaceutical University in 2000
- Master Degree in Technikon Pretoria, SA in 2004
- 10 years practical experience on international registration of medicines
- 7 year experience in WHO PQ programme as project manager and responsible for regulatory affairs focus on dossier preparation



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Content and Purpose

- **Content**
  - Brief history of PQ application for Dihydroartemisinin/Piperaquine tablets
  - Experience in application of PQ
  - Personal idea and suggestions on PQ application

- **Purpose**
  - To remind the pharmaceutical companies to operate prequalification project with good understanding to avoid the simple mistakes

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History of DHA/PQP PQ application

- 2005: First submission to WHO for DHA/PQP tablets
- 2007: A taskforce for PQ project was build
- 2007: Submit the 2nd version of application for DHA/PQP after self-promotion in both dossiers and GMP
- 2009: DHA/PQP included in EOI and we had official acceptance for MA 073
- 2010: Site inspection for FPP
- 2011: Site inspection for API of DHA
- 2012: GMP approval for API and FPP
- 2012: Bioequivalence study

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Difficulties and Problems

- 7 years from the first submission
- Why? What is the reason for such a big delay
  - EOI: no EOI product, no acceptance
  - Challenges in seeking PQ
  - Choice of manufacturer of API and site situation
  - Dossiers
  - Clinical study and/or BE study

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Challenge in seeking PQ

- The management is not clear with PQ programme: PQ does not fit for all the factories, it fit for:
  - Top management should understand the cost and benefit from PQ project and also know their own situation, PQ should support your strategy
  - Product in EOI list even in PQ list
  - Product market for a period of time (replace validation to save time)
  - API is controlled by the applicant
  - Hold product license and better to have BE study and quality study
  - Enough budget for update
- The technicians are not clear with PQ requirement and the PQ procedure
  - Lack of international staff, professional and English
  - Less knowledge and experience of ICH registration
  - The project is not under well evaluation and analysis, no good design on the budget and working plan
  - No risk control, phase control, even bonus for milestone

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Choice of manufacturer of API and site situation

- Before 2015, all the Chinese pharmaceutical manufacturing sites should update in compliance with the new version of SFDA GMP regulations
  - Good news: same level of GMP in SFDA and WHO
  - Bad news: hesitate to apply for which factory

- **My suggestion**: Do it now, you will never know how far you are from PQ if you do not start it

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Dossiers and BE study

- Misunderstanding of Prequalification requirement
- Dossiers preparation: simple description and no justification for always
- True, correct and logical
- Communication with WHO in technical level
- BE study for generic products

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Review of current status in China

- Only one manufacturer was prequalified: Guilin for antimalarial: 5 products
- Sites were approved for GMP compliance are less: FPP including Guiling and Nanhu; API including Chongqing Wulingshan, KPC, Desino, Huahai and Xinchang
- Some of companies are applying for API, some are preparing the dossiers, and many potential applicants are still thinking…

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Personal understanding of PQ project

What is benefit for Prequalification

Advantages of performing PQ

- Update GMP
- International staff
- Precursor (increase of tender, brand building, national support)
- Connect to international market
- Chain active promotion
- Sales and profit
- WHO assistance
- Facilitation of registration in Africa
- Social responsibility

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Conclusion

- PQ is a very good project which fit for some Chinese pharmaceutical companies
- PQ has big benefit and big challenge, be clear before you start it, better to have consultant for designing the works and avoiding the risks
- Keep in mind it is not a project for getting money, but to help people and promote yourself
- It is the beginning, far away from the end, we need continuous update
- We need help from WHO and all concerned people

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Good Luck To Everyone

谢谢

Thanks

Welcome to discuss for any further questions on PQ

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