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

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- 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
Content and Purpose

• **Content**
  – Brief history of application for DHA/PQP tablets
  – Experience in application and dossiers preparation
  – Personal suggestions

• **Purpose**
  – To remind the pharmaceutical companies to operate prequalification project with good understanding to avoid the simple mistakes
History of DHA/PQP PQ application

• 2007: A taskforce for PQ project was build
• 2007: Submit the application for DHA/PQP after self-promotion in both dossiers and GMP as an innovator product
• 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
Difficulties and Problems

• 5 years from the first submission
• Why? What is the reason for such a big delay
  – EOI: no EOI product, no acceptance
  – General understanding of Prequalification programme
  – Choice of manufacturer of API and site situation
  – Dossiers
  – Clinical study and/or BE study
Internal and external 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
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
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
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, Huhai and Xinchang
- Some of companies are applying for API, some are preparing dossiers, and many potential applicants are thinking…
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
Conclusion

• PQ is a very good project which fit for some Chinese pharmaceutical companies
• It 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
Good Luck To Everyone
谢谢
Thanks
Mercy

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