Article - The role of ISPE in Thailand



Pierre who is the chairman of ISPE Singapore has suggested an article about the role of ISPE in Thailand, in helping regulatory agencies. It could be a joint piece with Bob Tribe

Background to Pharmaceutical Industry in Thailand

Some History - 20-30 years ago

Initially a small number of international pharma companies (the multinationals) invested in the region, and established their own manufacturing bases. Meanwhile local companies developed to medium-sized private and family owned businesses (SME) with some knowledge transfer and sharing from multinationals to locals

Some History - 20 years ago

Tax privileges and government incentives attracts multinationals to relocate to regional hubs (Singapore, Penang etc). For example Singapore has a policy to attract pharmaceutical companies with long term tax incentives together with an international financial and a legal system which is attractive to foreign investors. Singapore has an attractive infrastructure which includes Universities and Technical Colleges with relevant courses to support the industry which produce enough trained graduates. A number of well known contracting and consulting companies are located there. Other Asean countries do not have this infrastructure.

Some History - 10 years ago

The investments made 10-20yrs were not generally maintained due to lack of external drivers, leading to:

- A focus on the local markets with only local expertise and experience
- Little international experience
- Very manual processes
- All data and processes on paper with a large amount of manual entry and transcription between sources.
- More isolated/legacy GMP practices, less standardization
- Modern IT tools not available to SMEs as seen as too expensive, some solutions from other industries (e.g. MRP as used in auto industry)
- Only Production and QC departments, no QA

Current Situation

The Asean group of nations have adopted PIC/S as the regulatory standard for the region. The formation of Asean and the move to PIC/S regulations has encouraged some local companies (Regional Leaders) to invest in new facilities.

The Regional Leaders are :-

- Externally focused
- May specialise in more complex dosage forms such as sterile products,
- Pursuing PIC/S compliance as an enabler of future growth regionally and internationally.
- Actively looking to ASEAN to expand their markets

What does a typical Thai company look like ?
A typical Medium Sized Pharmaceutical Production Company in Asean Region produces formulated product and packing. The company distributes its products to hospitals, wholesalers and major retail outlets often through government contracts. Some companies export to other Asean countries.
In this typical facility there is 600 staff, producing 200 products. The products are mainly OSD with 'conventional API' (no potent products), also liquids and creams.
A few companies also have some sterile production, typically LVP IV (saline and dextrose) and SVP typically optical solutions. In our typical facility there are 30 batches per week in multiproduct processing plant, with 'open ' processing, a typical batch is 1 million tablets.

The Market
Today Pharma Companies are facing pressure on their business from 2 directions

- First there is pressure on healthcare budgets caused by rising numbers of older people, and fewer young people having children. The governments in Asean countries fix the prices paid for medicines used in the public hospitals. These prices are low compared with prices in the west. Each year the governments hold an e-bidding process to establish contracts for the main medicines used in the hospitals. The medicines sold to public hospitals are usually generic brands made by a number of local companies.
- Second is the pressure from the adoption of the new regulations. and these new regulations are just coming into force. As a result companies are having to invest in new facilities and new ways of working. Companies that do not invest will not be allowed to continue operation.

ISPE

ISPE Thailand formed in 2003, we were the second affiliate in the Asean region

- Singapore Affiliate 2000
- Thailand Affiliate 2003
- Indonesia Affiliate 2007
- Philippines Affiliate 2008
- Malaysia Affiliate 2011

Meetings

The Thai affiliate has a main objective to help the industry come up to international standards with a rolling program of 4 meetings per year. We use our contacts to provide materials training and material covering :-

- Training on hot topics with some Internationally recognised trainers
- Use of Baseline Guides and Good Practice Guides to help with the design of the new facilities
- Understanding of the new thinking, QMS, quality risk management, validation
- Managing differences in expectation 1st world vs Emerging nations.

We have had successful meetings covering :- GEP, URS, Commissioning and Qualification, Water Systems, HVAC, Risk Management, Cross contamination,

Thai FDA

Because the ISPE is a non profit organisation we can invite the Thai FDA. The Thai FDA have recognised the role that we provide and they always attend and we have provided specific training for them .

Yesterday there was a Thai Industrial Pharmacists Association (TIPA) meeting here in Bangkok and at the meeting the Thai FDA announced the outcome of the recent inspections by the PIC/S auditors who accompanied the Thai FDA on 3 recent inspections of local companies, Silom Medical, Unison and Mega Lifescience. The expectation here is that Thai FDA will get the PICS certificate maybe this year or maybe early next year. Our ISPE program has helped the Thai FDA to get to this point.