Workshop on generation and use of HBEL

EMA

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Field challenges faced with HBEL

- **Getting the concept through** : Some companies are still naïve to the requirements of HBEL approach and still haven't taken it into consideration. Although segregation by group of products is in place, the HBEL data is still absent in the rationale.

- **Purchased / Supplied PDE data** : (mainly the case with contract manufacturer) absence of internal review: the data is simply compared with MACO, no further interpretation nor intergration in the pharmaceutical quality requirement, solely used for cleaning validations, non specific

- **High pharma expertise** : companies with toxicologists on board show a high understanding, difficult for inspectors to challenge.

Contact

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