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Maximise your ROI when Acquiring a Portfolio of Marketed Products

Product acquisition and product swaps increased from $105Bn in 2012 to $254Bn in 2017. Acquiring a product already on the market means you dispense with the development risk and maturity usually correlates with a more stable safety profile. However, as products age and become available in more markets, so the number of changes to their CMC and labelling can be expected to accumulate.

Every such change increases the risk that the CMC and registration dossiers become out of sync. While acquisitions can often bring these discrepancies to light, the rapidity of deal processes means it will most likely become apparent post deal signature. Completing a full Due Diligence pre-signature is challenging because:

The volume of dossiers is large given one registration dossier per product per market	Deal teams are rarely comprised of experts with the depth of knowledge required to make these judgements even though the cost of remediation could be material to the deal
Comparing registration and CMC dossiers can be an arduous, manual process as they are often stored in separate non-communicating systems	The system data is often inaccurate; confirming compliance generally requires contacting pharma manufacturing sites, third party manufacturing sites and the Regulatory Affiliates

Potentially your product could be withdrawn from markets where non-compliance is uncovered, meaning: patients are denied access to their medication, revenue from your acquisition is interrupted, dossier remediation adds cost, your likelihood of inspection increases and your reputation with Health Authorities and patients/payers is tarnished.

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Kinapse “Product Acquisition Support Service” (PASS) encompasses a suite of services to help Buyers and Potential Buyers mitigate their risks, avoid costs and maximise their ROI. The PASS team can be engaged at any point from pre-sale to post signing. Services include:

Buyers start with contracts which mitigate the risk of remediation costs if the portfolio is highly non-compliant. The objective risk assessment means buyers choose the level of risk for due diligence with which they are comfortable and remediation provides peace of mind. The upshot is mitigated costs, assured revenue and hence maximum ROI.

If you would like to learn more about PASS, or any other aspect of Regulatory Maintenance, please don’t hesitate to get in touch:

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