

sounding stuff! Well, it should be as I lifted those words from the FDA website. But why do you exist? You exist because bad medicines kill people and those people tend to be voters. Any Government knows that being in charge and doing nothing when people are dying doesn't tend to win elections in a democracy. There are no positives about bad medicines and there's no way to spin this.

When something goes wrong then you need to investigate and take action (often legal enforcement). In light of this, you tend to do audits of facilities and enforce compliance to standards which you also develop. But there's a problem. The pharmaceutical industry is a global and complicated supply chain. The drugs in your local chemist shop probably were delivered through a series of warehouses and transportation systems (facilities) with plenty of opportunities for things to go wrong. Before this it was manufactured (in another facility) with the active / inactive components being chemicals which themselves were delivered through a series of warehouses, import/export, transportation systems and manufacturers. Even the raw material to make the chemicals can come through another set of facilities which can include refiners and miners. The supply chain can be very long, very complicated and provides many points where disaster can be introduced. It's also global and when you cross international borders then you have no guarantee that the standards which you apply are also the standards that are in practice applied elsewhere. Which is why you, as a regulator, probably push for global standards and close co-operation with other agencies. You work with other nations to develop supply chain toolkits covering good