



patient safety

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16th Annual
Pharmaceutical
Compliance
Congress

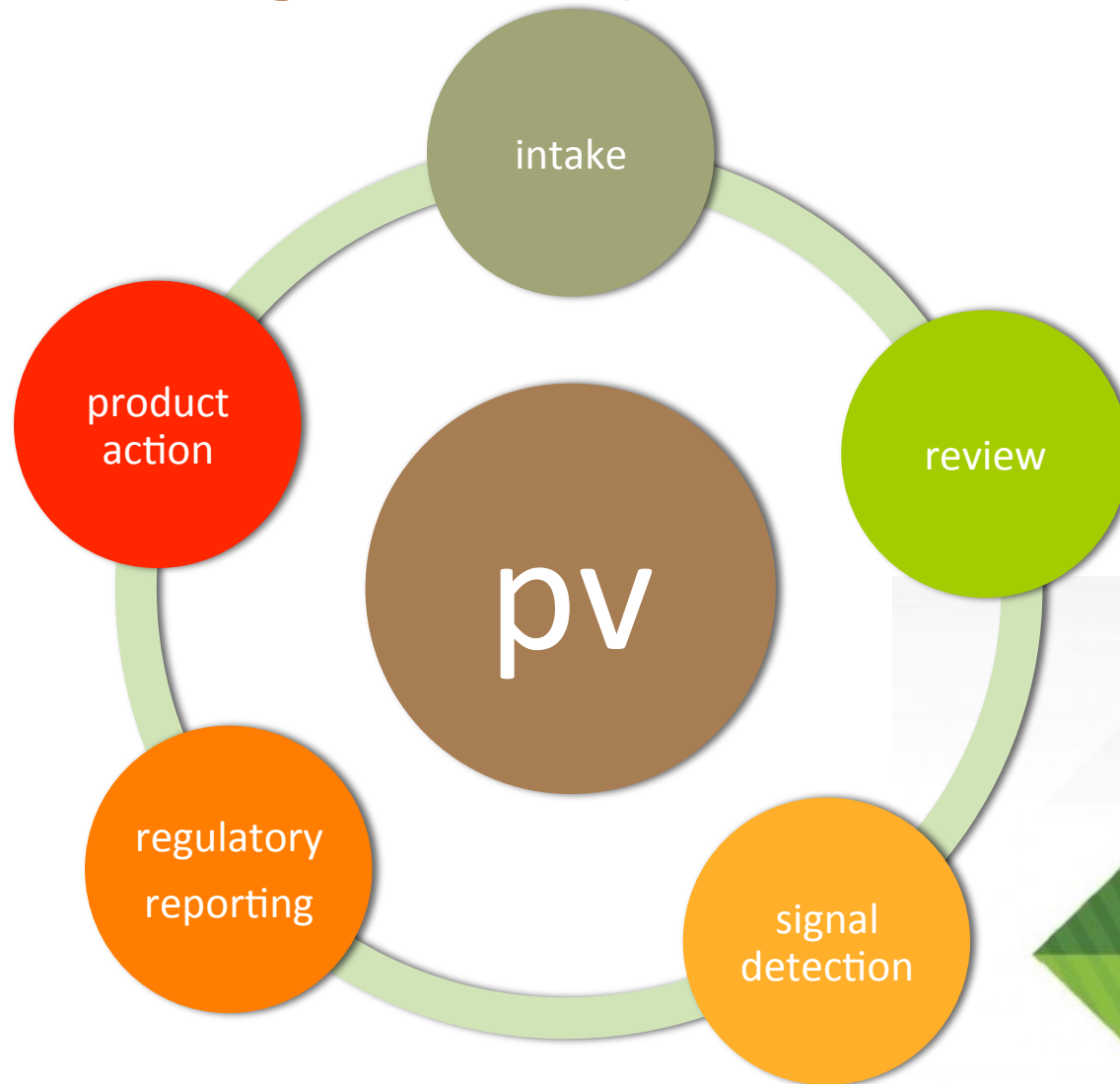


Whitelaw Compliance Group, LLC.

center of everything



pharmacovigilance cycle

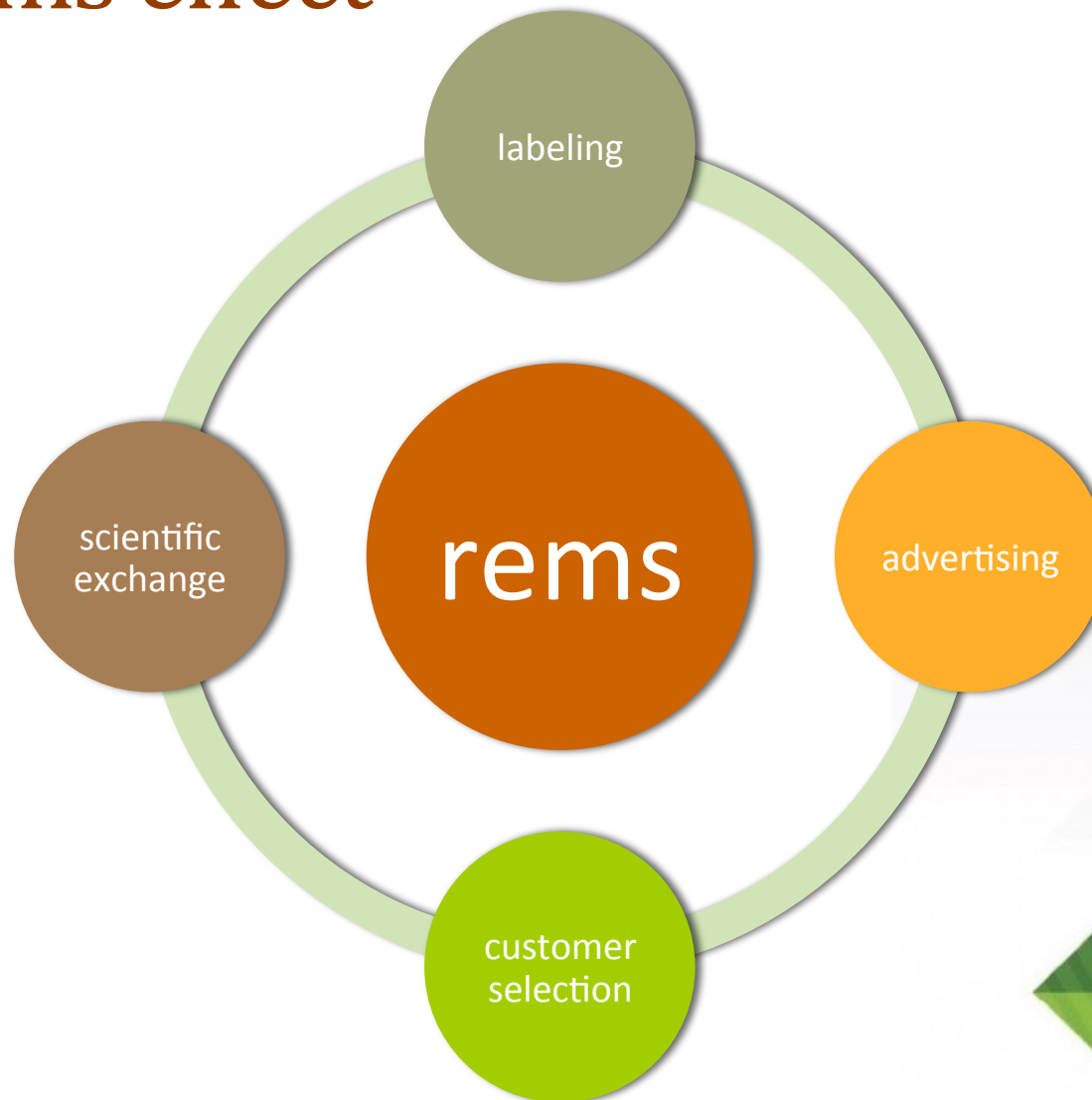


some compliance watch outs

- who is making the ultimate safety decision and to whom does he or she report?
- if the PV head and ultimate decisionmaker are different how are differences resolved?
- are there multiple reporting systems or multiple instances of the same system that don't communicate well?
- what types of metrics are being monitored (e.g., backlogs)
- do the company auditors really have the expertise in pv?



the rems effect



rems controls



- medication guides



- communication plans



- elements to assure safe use (etasu)
 - training
 - provider/dispenser certifications
 - dispensing in controlled situations or settings
 - patient monitoring or registries



- implementation system



compliance watch outs

everything centers
around

Implementation



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helping companies grow sustainable integrity

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