Brand Protection Needs in the Pharmaceutical Industry

The Global Problem of Counterfeit Pharmaceuticals
Assessing Risks As Part of a Brand Protection Program

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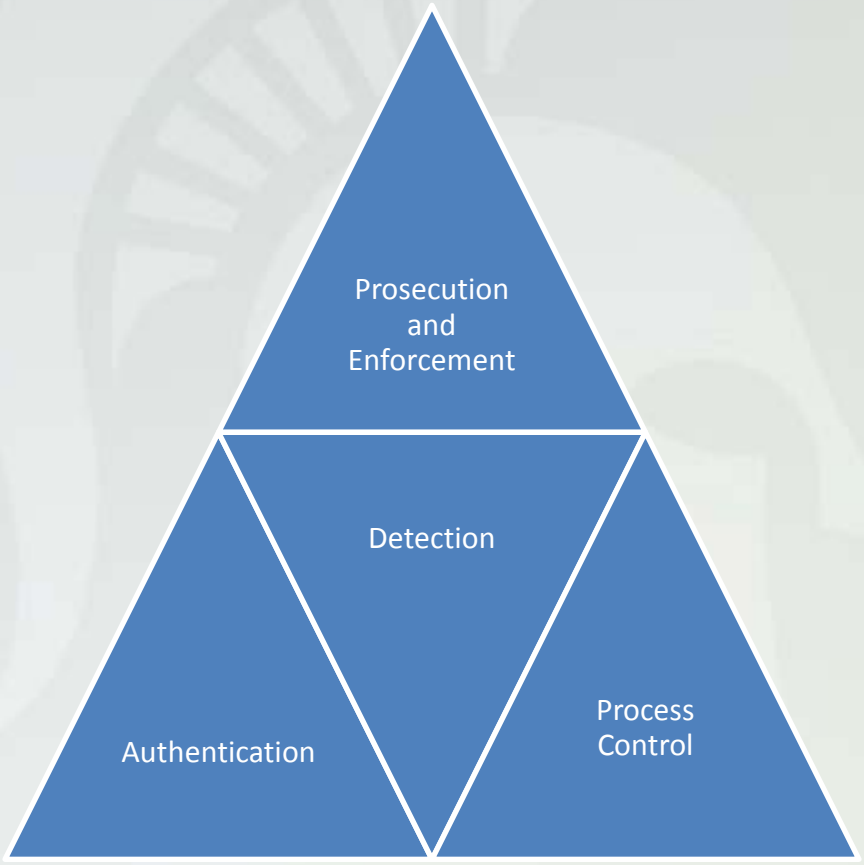
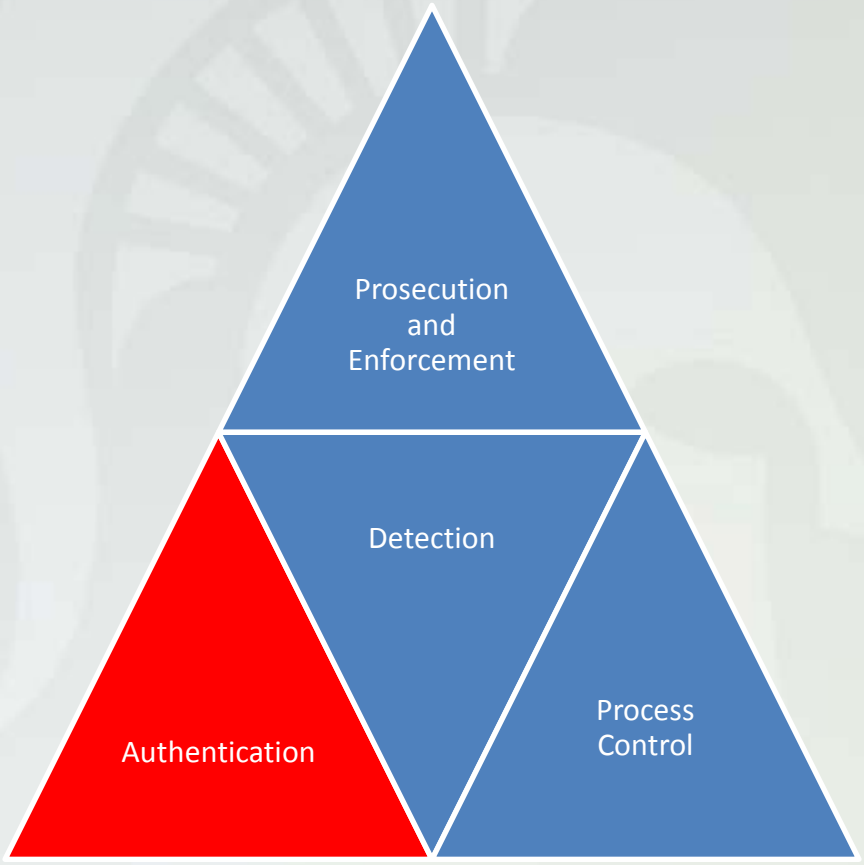
February 20, 2014

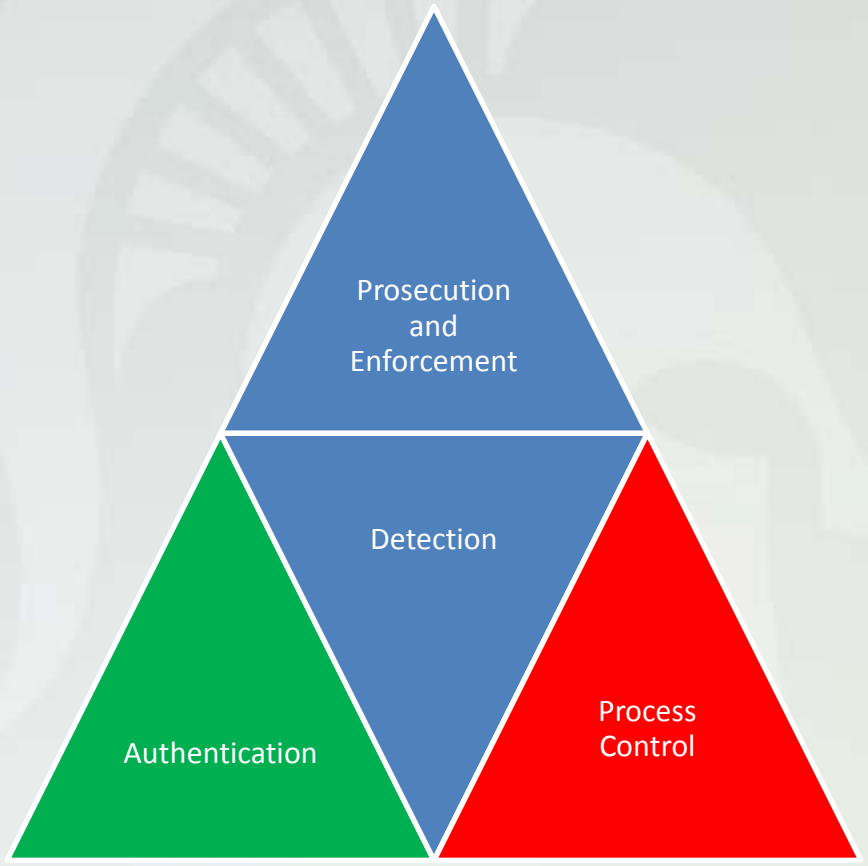
Building for Success – Basic Principals In Brand Protection



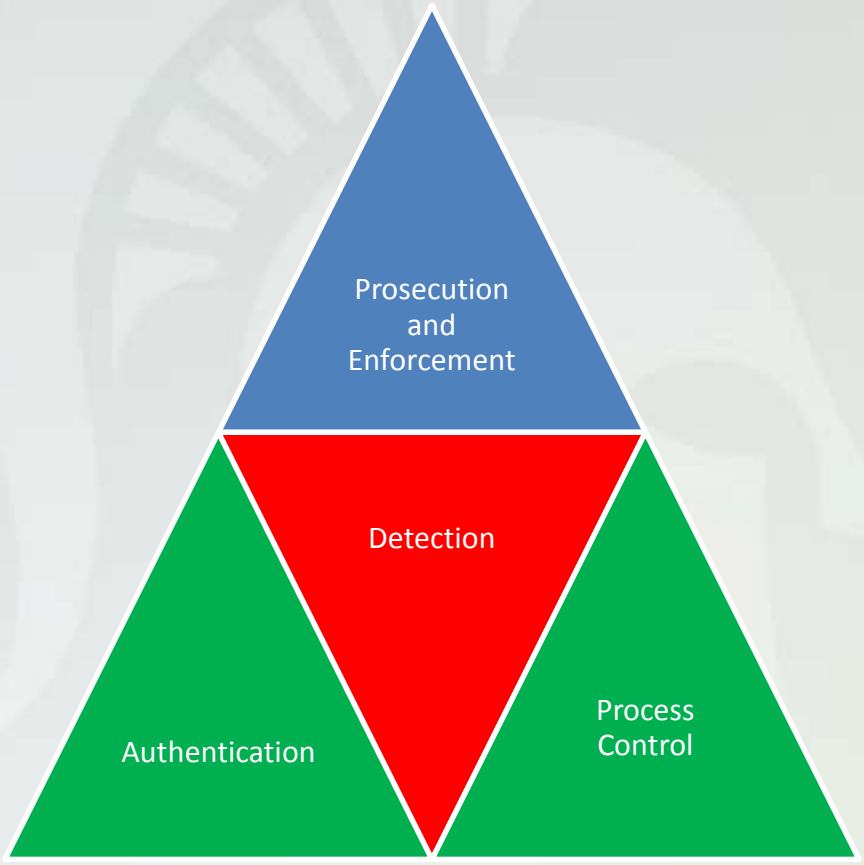
Authentication – What Makes This One True and Originally Ours???



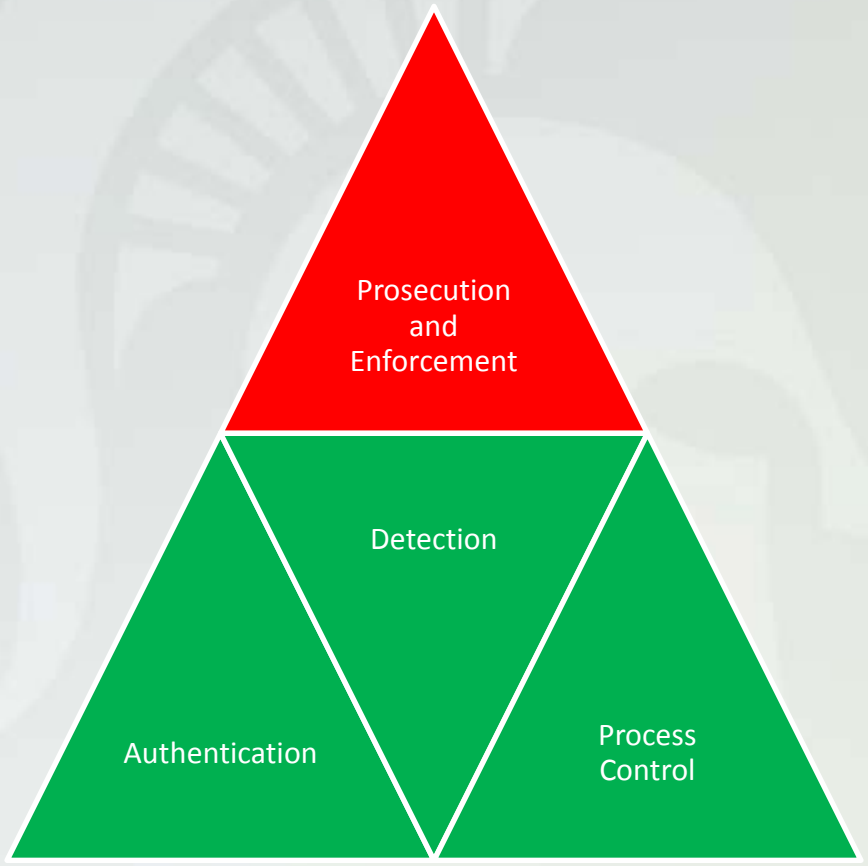
Track and Trace - Where Is The Product Headed, Where's It Been, Where Is It Now?



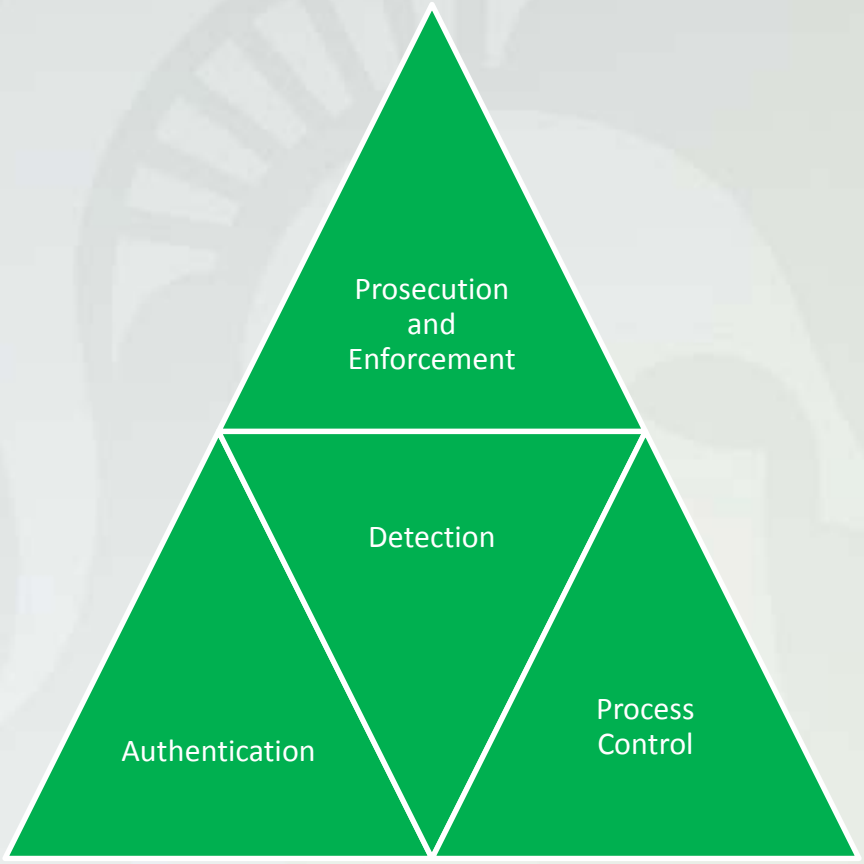
You Cannot Prosecute What You Cannot Find, So You Must Detect.



Making Use of Your Findings, Making It Hurt, Making It Stick, Making It Public…



Holistic Approach To Brand Protection



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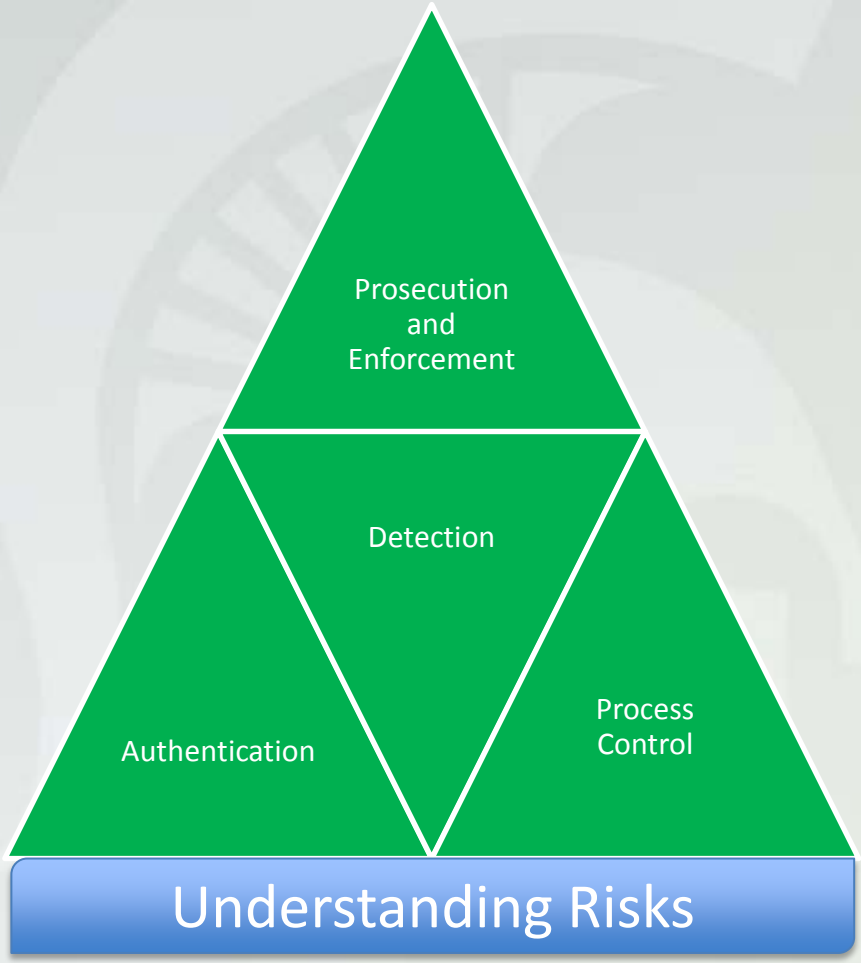

Assessing Product Risk

Spreading the “Big Six” thinking

R&D Understanding and Integration

Product and packaging considered

Manufacturing and Packaging locations reviewed

Distribution locations and processes reviewed

Pricing strategies feeding diversion trends

Logistics strategies feeding counterfeiting trends

Company practices feeding both

The Big Six Questions…

1) To your knowledge, has this product class or brand ever been counterfeited?
2) To your knowledge, has this product class or brand ever been illegally diverted?
3) Have you ever looked for counterfeit or diverted product in the marketplace?
4) Have you ever investigated the return goods process to determine the type and flow of products being returned?
5) Have you ever investigated the product complaint history process to determine if product tampering or diversion may be misreported as miscellaneous complaints?
6) Have you ever investigated the product and packaging destruction process to determine adequacy and thoroughness of product destruction?

The Remaining Questions…

There are additional questions used to drill down to the potential sources of and insights into product, market, and regional factors that can lead to increased ease in counterfeiting and illegal diversion of products.

A team effort is needed to understand how products are developed, marketed, distributed, repackaged, reprocessed, dispensed, consumed and disposed.

Requires looking upstream and downstream, from sourcing through manufacturing , in distribution through your chosen channels.

Requires understand this level of detail globally, not just domestically.

MICHIGAN STATE
UNIVERSITY
Center for Anti-Counterfeiting
and Product Protection

A-CAPP
Paper Series

Assessing the Risks of Counterfeiting and Illicit Diversion for Health Care Products

Christopher Trent
Senior Manager
Product Protection
Johnson & Johnson Global Brand Protection

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Adjunct Instructor
Program In Public Health
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November 2013

For More Information on Risk Assessment Please Consider The Following

- http://a-capp.msu.edu/sites/default/files/HealthCareProductsRisk_Trent_PaperSeries_FINAL.pdf

If Risks Exist, Protect…

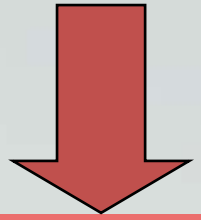
Product Protection is . . .

- Assessing the risk to each product
- Protecting products AND packaging
- Developing product protection standards
- Deployment of product protection features

Product Protection is not. . .

- Slapping features on products to solve unknown problems
- An inexpensive way to improve defects in packaging design

Assessing Where You Are



	Secure Supply		Program Management		Monitor
No features	Security Features	Common Security Features	Common Security Features With Supplier Program Mgmt	Common Security Features With Integrated Program Mgmt	Common Security Features With Integrated Program Management and Effective Monitoring
• Commodity feature deployed OR • Inconsistent application of the feature OR • Monitoring device not available or not developed to enable authentication	• Proprietary feature deployed • Little to no operating company oversight to manage the feature • Feature is not standard across the sector • No monitoring plan • No formal integration into product design or bill of materials • Monitoring device available to authenticate product	• Standard proprietary feature deployed • Little to no operating company oversight to manage the feature • No monitoring plan • No formal integration into product design or bill of materials • Monitoring device available to authenticate product	• Standard proprietary feature deployed • Management of the supply process by the Supplier • No/informal monitoring • Monitoring device available to authenticate product	• Standard proprietary feature deployed • Management of the supply process by the Supplier and OpCo • Formal integration into product design and bill of materials • No/informal monitoring • Monitoring device available to authenticate product	• Standard proprietary feature deployed • Management of the supply process by the Supplier and OpCo • Formal integration into product design and bill of materials • Formal monitoring program identified and resourced • Formal training kits created for monitoring programs

Determining How To Advance

No features	Security Features	Common Security Features	Common Security Features With Supplier Program Mgmt	Common Security Features With Integrated Program Mgmt	Common Security Features With Integrated Program Management and Effective Monitoring
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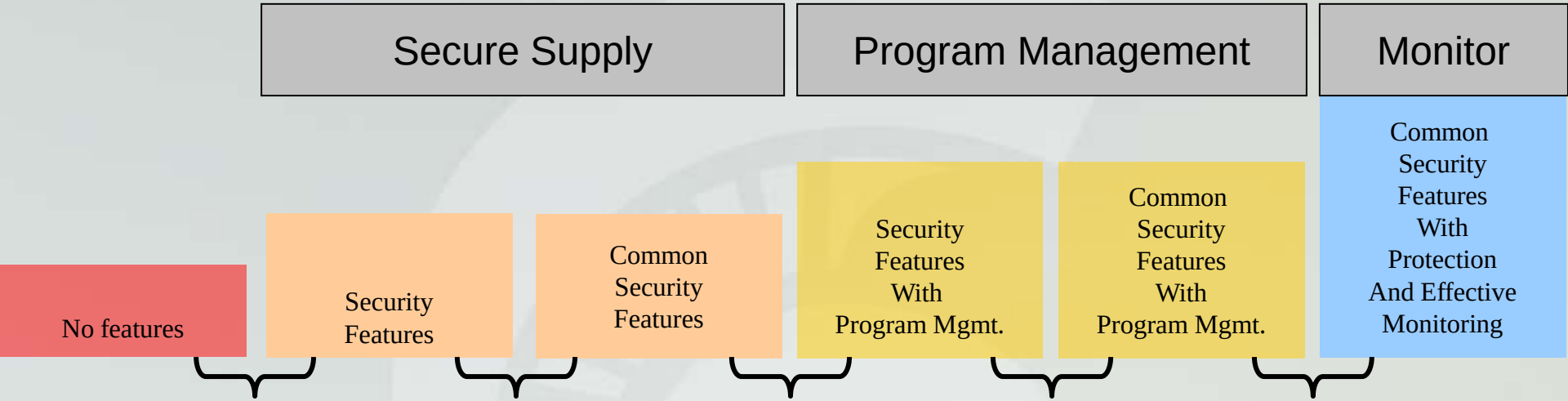
How To Move Forward



- ✓Evaluate options for features
- ✓Review product Supply Chain specifics
- ✓Develop an effective feature for monitoring
- ✓Ensure ability to monitor throughout the supply chain
- ✓Reliable Source of Authentication from RFI

- Implement the standard security feature used across the sector
- Implement from Known Authentication Providers

- Interject program management by the Supplier
- Monitoring forecasts and utilization of the feature

- Interject program management

- Identify and resource formal monitoring program
- Create formal training kits for monitoring programs (returned goods, customs, and field monitoring)

Thoughts On Technology…

- Know what problem you are trying to solve first.
- Get as close to the product as you can do so affordably.
- No single technology can assure a product will not be counterfeited.
- Layers must be utilized and features must be changed, stay nimble.
- No technology should be deployed without a plan for monitoring it in the field, ever.
- No technology should be deployed that cannot be updated in a moments notice.

Incident Management

- Every new incident should be measured against the Product Risk Assessment Questionnaire
- Questions should be updated if they are found to be inadequate or incapable of detecting counterfeit, diversion, or tampering risks.
- Annual review of questions a must
- Never stop updating and improving

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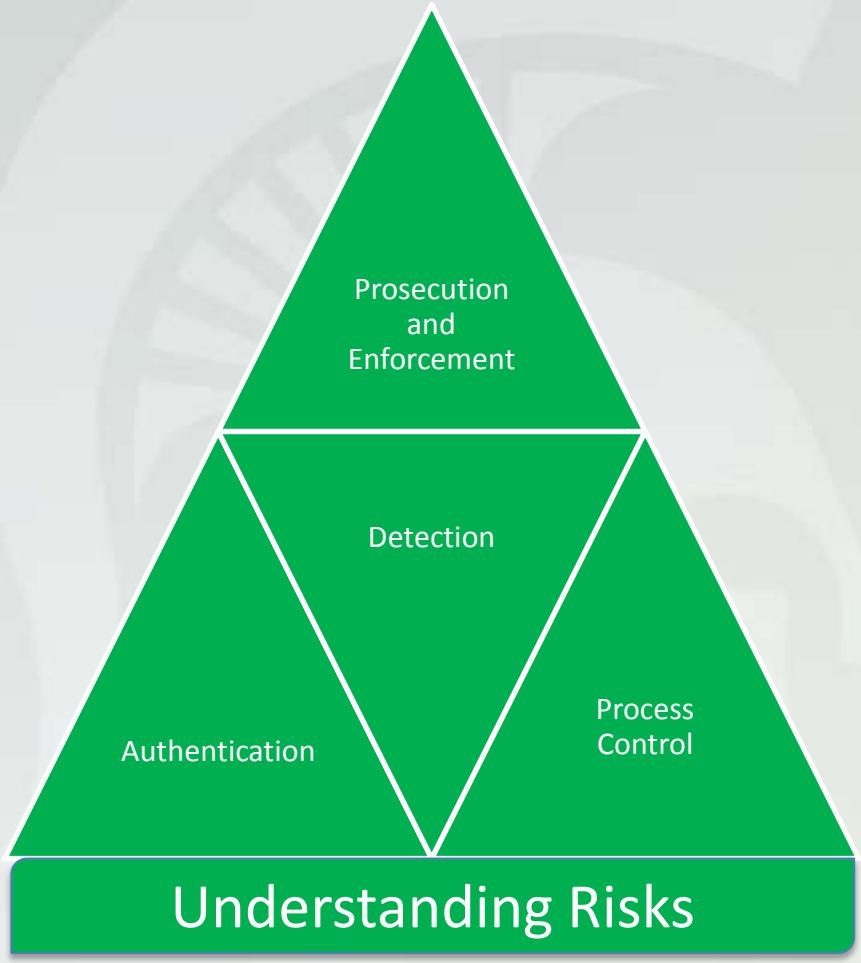

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Thank You

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