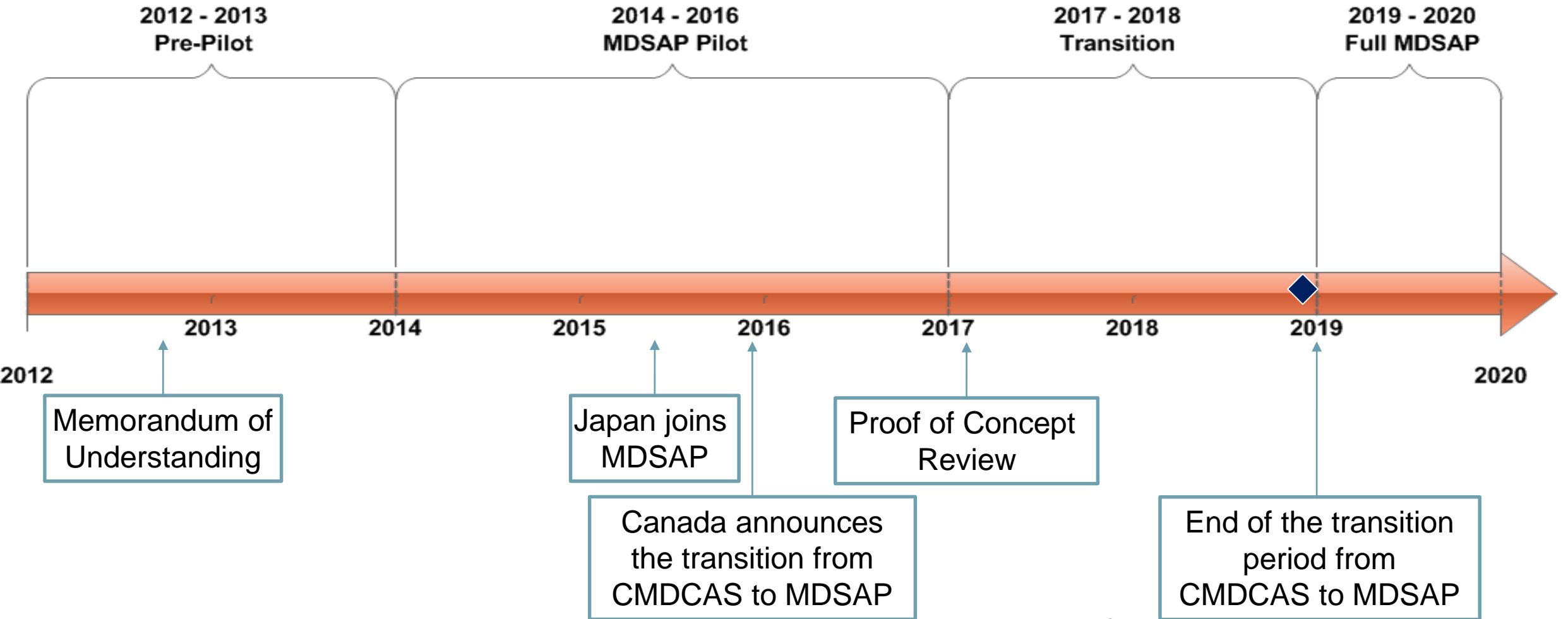


Status of Recognition of Auditing Organizations

Marc-Henri Winter
US FDA

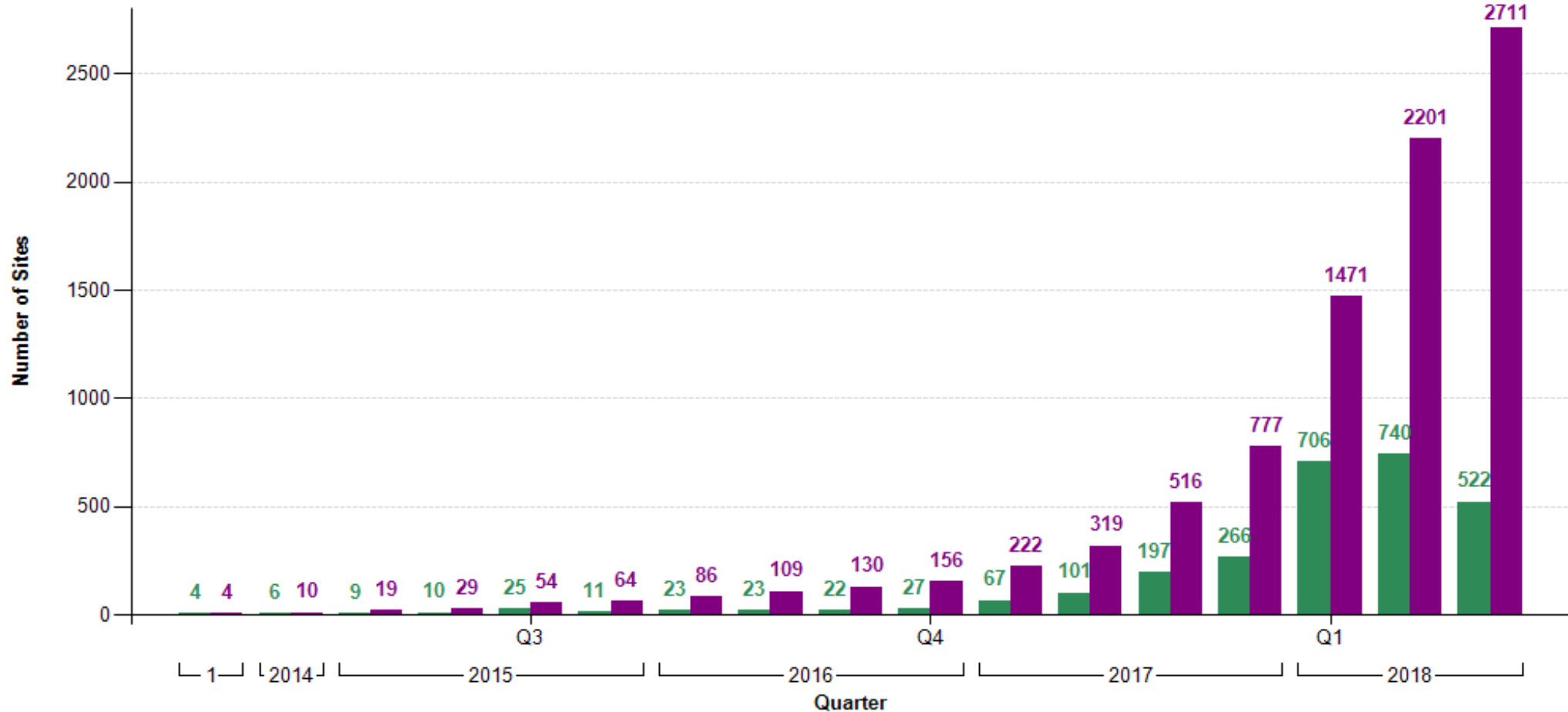
Timeline

















Manufacturer Participation

Up to 2018-08-31

Number of Sites Added Cumulative Total



Auditing Organization Participation

Authorized to Conduct MDSAP Audits	Recognized
 <p>Lloyd's Register LRQA</p>  <p>QMI™ SAI GLOBAL</p>  <p>NSF</p>	 <p>LNEG MED</p>  <p>NSAI National Standards Authority of Ireland Údarás Um Chaighdeán Náisiúnta na hÉireann</p>  <p>bsi.</p>  <p>TUV USA Member of TÜV NORD Group</p>  <p>DQS MED</p>  <p>intertek Total Quality. Assured.</p>  <p>DEKRA</p>  <p>TÜV SUD</p>  <p>UL</p>  <p>SGS</p>  <p>TÜVRheinland®</p> <p>Current, as of 2018-01-26</p>

Authorization vs. Recognition

- Both groups have undergone their on-site assessment and favorably corrected any deficiencies
- Both groups can conduct MDSAP audits and issue certificates
- Authorized Auditing Organizations may still need to undergo witnessed audits before recognition
- Recognized Auditing Organizations will undergo periodical surveillance witnessed audits



Questions