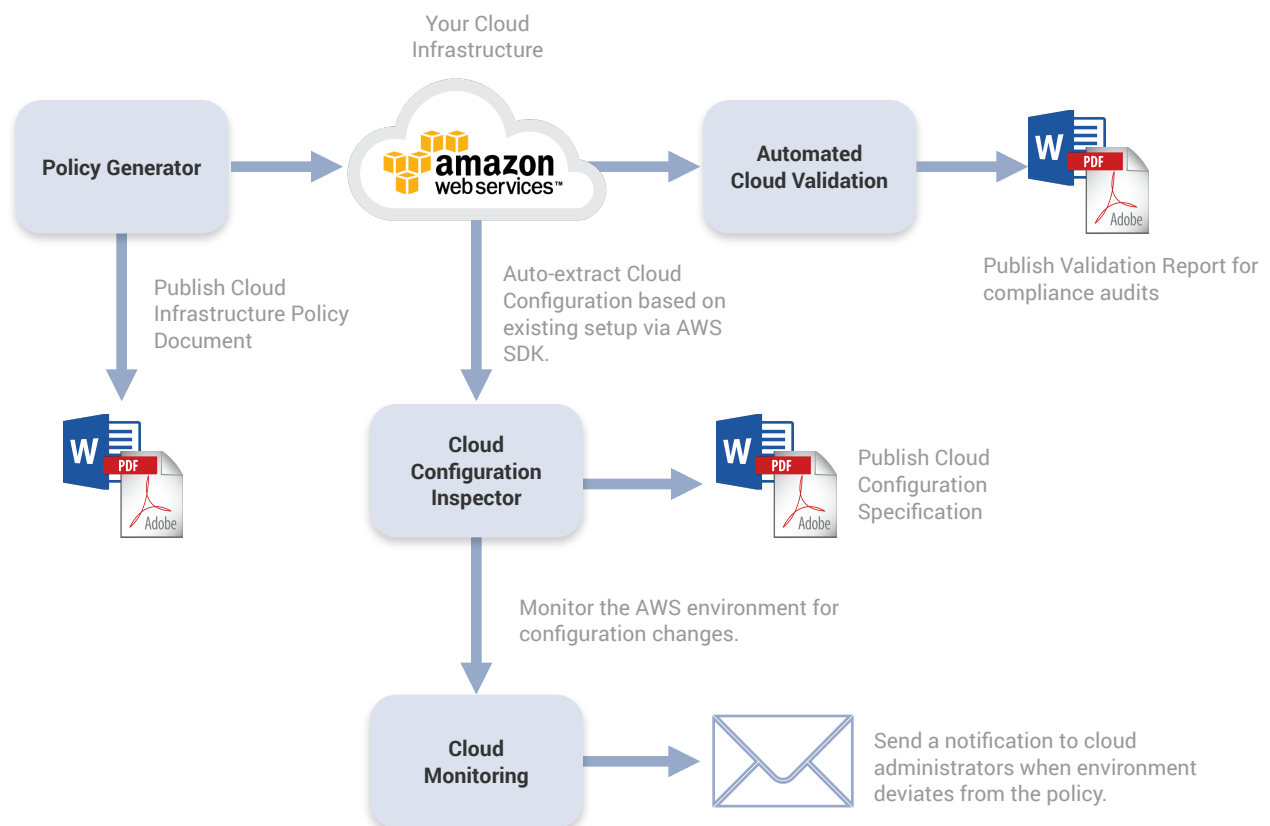# Automated Cloud Compliance

GxP and 21 CFR Part 11 Compliance

Sierra Labs has developed a set of tools to help companies with HIPAA compliance, 21 CFR Part 11 requirement, and GxP validation and verification processes for cloud hosted solutions. The following are a list of features and capabilities of our Automated Cloud Compliance product:

- Generate cloud infrastructure policies and procedures for your organization.

- Auto-inspect your current cloud infrastructure and extract the configuration specifications.

- Automate the monitoring of your cloud configuration and alert administrators when changes deviate from your policies.

- Execute validation and verification tests against your cloud infrastructure and generate a compliance auditable report.

- Publish policies, configuration specifications, and validation reports using your own templates that meet your organization's compliance standards.

Your Cloud Infrastructure

Policy Generator

amazon webservices™

Automated Cloud Validation

Publish Validation Report for compliance audits

Publish Cloud Infrastructure Policy Document

Auto-extract Cloud Configuration based on existing setup via AWS SDK.

Cloud Configuration Inspector

Publish Cloud Configuration Specification

Monitor the AWS environment for configuration changes.

Cloud Monitoring

Send a notification to cloud administrators when environment deviates from the policy.

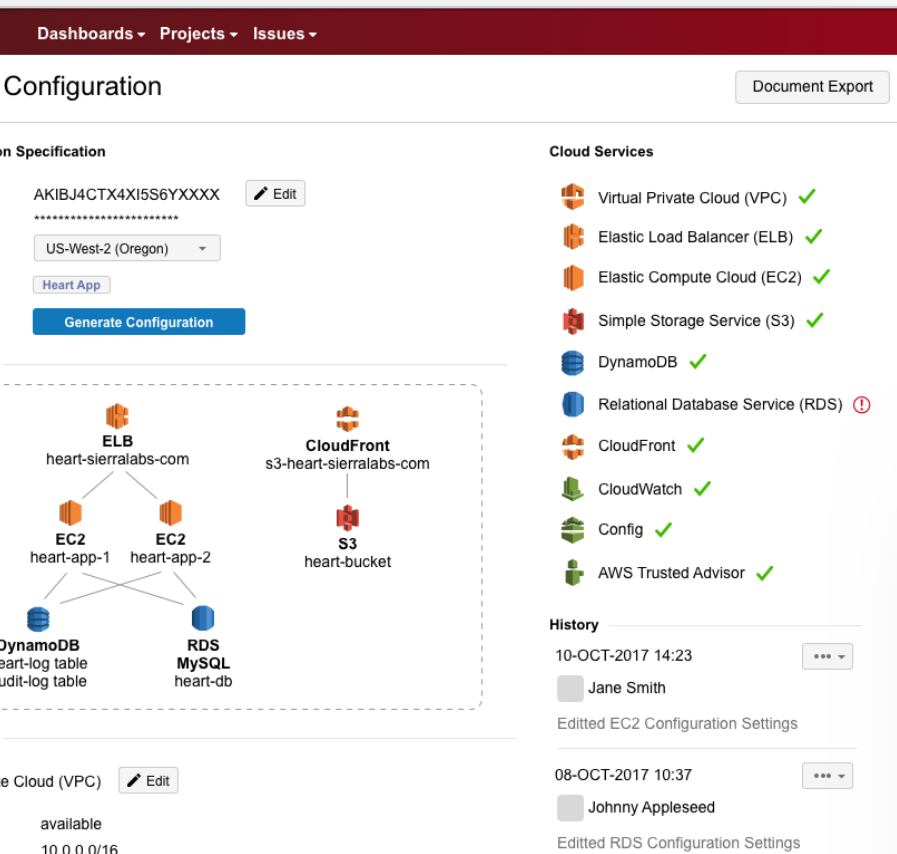# Cloud Infrastructure Policy Generator

Generate an AWS Cloud Infrastructure Policy based on the AWS services you are using. Our database of recommended policies and procedures are proven industry standards. We have aggregated GxP best practices, AWS industry standards for security, and HIPAA compliance guidelines. Policies and procedures defined in the system can be enforced in AWS configuration.

- Context aware - allows the system to enforce the policies and procedures.

- Database of policies, procedures, and templates for Medical Device, BioTech/ Pharma, and Clinical Research applications.

- Traceability - all of our policies, procedures, and templates are traceable to FDA guidance, regulations, GxP best practices, and HIPAA policies.

- Built-in Intelligence - define only the policies and procedures you need based on your organization or team size. As you grow the system will alert and adapt with you.
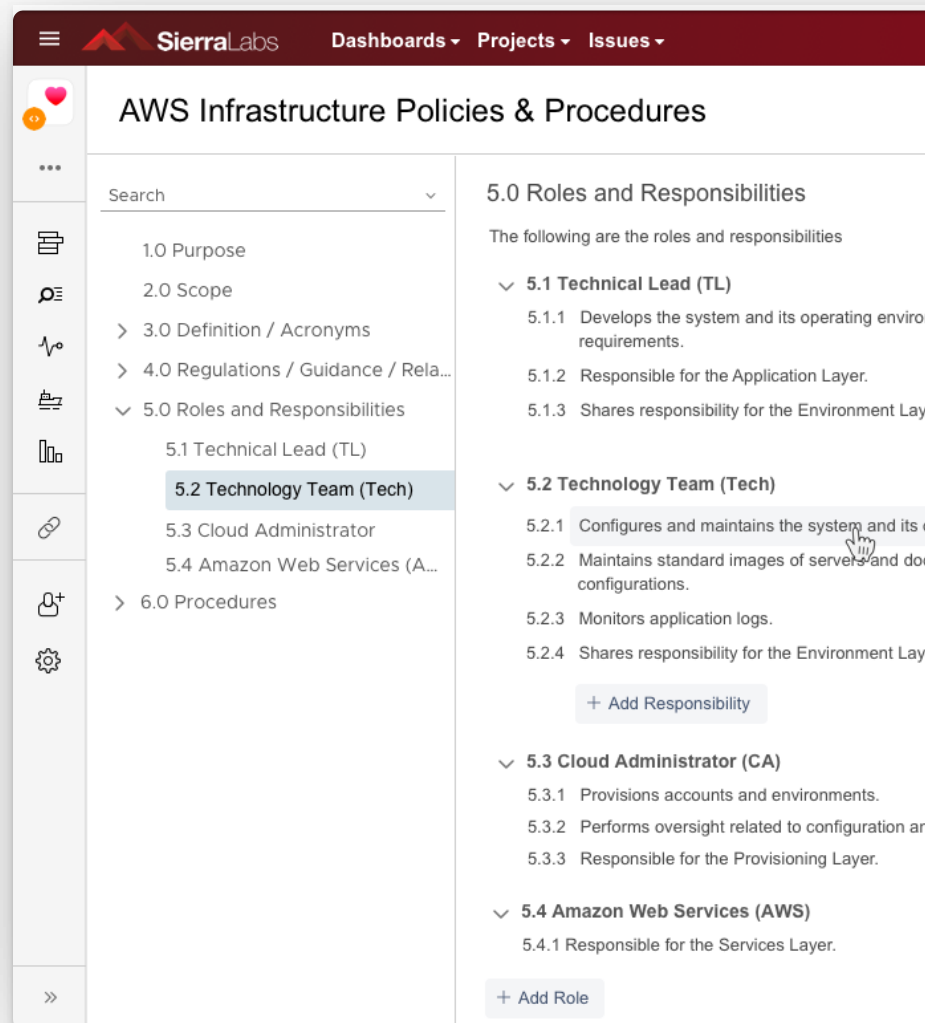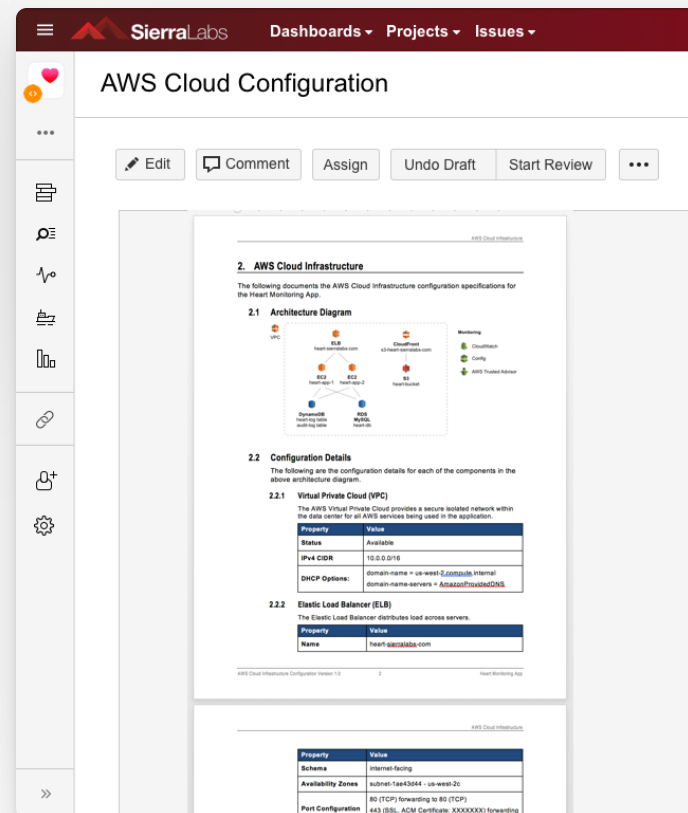
Cloud Configuration Inspector

Remote inspect your existing AWS account to determine all AWS services being used and the configuration of those services. The results can be published into a cloud configuration specification document.

- Using the AWS SDK we can remote inspect the cloud services you are using and generate the configuration specification.

- Instantly identify configurations that deviate from your cloud infrastructure policies.

- Publish the cloud configuration specifications into an MS Word or PDF document for quality compliance review.

- You can provide your own custom template matching your SOP guidelines.

Continuous Cloud Validation

SierraLabs

Remote inspect your existing AWS account to determine all AWS services being used and the configuration of those services. The results can be published into a cloud configuration specification document.

- Generate a validation report that shows the AWS cloud environment meets the defined policies and configuration specifications. These reports can be presented during compliance audits.

- Monitor the AWS cloud configuration for changes and alert your cloud administrators when changes deviate from the defined policies.

 www.sierralabs.com

About Us

Sierra Labs is focused on aligning engineering/IT teams with quality and compliance teams in FDA regulated environments. Our QMS, cloud validation, and automation products are designed to be easily adaptable in pre-existing workflows and assist teams in producing validation and verification artifacts needed in high quality environments.

For more information, visit sierralabs.com.

Set up a demo with us.

Connect with us! We're compliance experts who can help you.

www.sierralabs.com   hello@sierralabs.com   (310) 853-1175