Proposal for Approval

**1.What & Why**

**What**: The goal of our App is to help an auditor (either for a FDA inspector under the guidance of ISO 13485 or for a BIQS auditor under the guidance of TS16949-ISO9001 ) to conduct a more efficient and more convenient audit for a medical device factory or automotive parts factory. The Auditor will need to open this app, scan an auditee’s equipment with back camera, then with machine learning technology, the app will show the auditor

1. the name of this equipment,
2. the standard operation procedure of this equipment, and
3. historical calibration record of this equipment.

**Why**: Manufactories in North America need to be audited by BIQS for every 6 months if they make automotive parts for GM and Ford, and also need to be inspected at least every 2 years by a FDA inspector if they make medical devices. The Auditor’s time is very precious while the auditor’s knowledge is limited. Most of the time, they will not know the name and functional purpose for every single measurement device/analytical equipment in the auditee’s Lab (they do not need to know all these). The things that a auditor really need to know are:

1) is this device been calibrated before use,

2) how often should it be calibrated according to the standard operation procedure,

3) where can I find the historical calibration record.

So, with our app (Machine learning + Database), auditor can easily get all these information. Quality assurance can then be improved in the long term: the auditor can conduct more efficient/accurate auditing, patients and car owners can have better quality products, and factories will have less recalls

**2.Expertise Link**

**Zhimo** is an expert in machine learning, and he is also a Phd student who’s interest is soft computing.

**Yaowen** is an America Society of Quality certified Quality Engineer with 2 years pre-clinical anti-cancer drug research experience under regulation of FDA and 4 years automotive manufacturing experience under regulation of TS16949-ISO9001.

We believe, with the combination of our expertise, North America’s quality assurance system can achieve the next level and will keep ahead in the Fourth Industrial Revolution (Industry4.0).

**3.Name**

OneScan