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# ANN risk beräkning vid tillverkning av medicin med automatiska system

## ANN risk calculation when manufacturing medicine with automatic systems

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## SAMMANFATTNING

**H**är är sammanfattningen. Sammanfattningen ska skrivas på svenska och kortfattat summera rapportens innehåll på tio till femton rader samt ett antal nyckelord (högst tio stycken). Sammanfattningen ska kortfattat redogöra för problemställningen och dess relevans, lösningen och resultatet så precist som möjligt. Sammanfattningen ska kunna läsas fristående och inte innehålla referenser och specifika akronymer som inte förklaras.

### Nyckelord

FDA Warning letters(WL), FDA Form 483 (pre-WL),FDA 21 CFR Part 11 recommendations



## ABSTRACT

A "proof of concept" application based on artificial intelligent and artificial neural network (ANN) that support drug manufacturers on which security categories the software for device or integrated devices in automated system belongs to. need to decide wiche categories with the decision process when Categories the device it comes to developing automated systems. the particular decision process the application is going to support is the Software Categories the device or integrated devices belongs to.

### Keywords

Keywords, More Keywords



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## INTRODUCTION

## 1.1 Background

One of the preliminary steps to completing a thesis is the background study for it. The background study for a thesis includes a review of the area being researched, current information surrounding the issue, previous studies on the issue, and relevant history on the issue. Ideally, the study should effectively set forth the history and background information on your thesis problem.[3][4]. The purpose of a background study is to help you to prove the relevance of your thesis question and to further develop your thesis. PM laid the foundation for modern artificial intelligence. Alan Turing published the journal *Computing machinery and intelligence*[8]. 2005 the Blue Brain project (BBP) was launched where the ultimate goal is to reconstruct and simulate the human brain[2]. 2011 IBM's super computer Watson wins in jeopardy[7].

### 1.1.1 subsection Example

bul bul som more sub bul

## 1.2 Problem Statement "Problemformulering"

Here the specific questions and problems should be described. It should be proper questions that end with question marks. Often a report will contain several different problem statements, questions, that are interrelated. Normally, it should be two to four questions and problem statements. Examples on common questions (simplified and generalized): • Can you use technique/approach X to get the effect/result Y? • How can a system, or solution, for X be realized such that it

results in effect Y? • What alternatives are there to achieve/obtain X and which alternative gives the best effect with respect to Y and Z? (This problem statement is best broken down into two separate statements.) Note that a very specific problem statement almost always yields a better thesis than a general statement. It is simply much more difficult to make sense out of a general statement.

### 1.3 Purpose

Your introduction has two main purposes:

- 1) to give an overview of the main points of your thesis; and
- 2) awaken the reader's interest. It's not a bad idea to go through the introduction one last time when the writing is done, to ensure that it connects well with your conclusion.

Tip: For a nice, stylistic twist you can reuse a theme from the introduction in your conclusion. For example, you might present a particular scenario in one way in your introduction, and then return to it in your conclusion from a different – richer or contrasting – perspective.

Your introduction should include:

The background for your choice of theme  
A discussion of your research question or thesis statement  
A schematic outline of the remainder of your thesis

The sections below discuss each of these elements in turn.

What is the purpose of the work? What is it heading and what should it accomplish?

The best way to formulate a good and specific statement is to make a detailed theoretical study and understand related research results and practice. This study would also spawn new ideas and build up a terminology which enables ways to express yourself precisely and also have valid standpoints for the discussion chapter. Also, with a detailed problem statement, it will be easier to outline a good method and perform the actual work much faster than if you start with vague statements. It is therefore wise to initially spend more time to do a good theoretical study. The supervisor will help you to judge when the problem statement is detailed and specific enough.

### 1.4 Restrictions "Avgränsningar"

AI is divided in to many categories and sub categories that in a thesis this size each category could at best be mentioned. focus had to be directed only on the parts the author deemed necessary.

One of the first tasks of a researcher is defining the scope of a study, i.e., its area (theme, field) and the amount of information to be included. Narrowing the scope of your thesis can be time-consuming. Paradoxically, the more you limit the scope, the more interesting it becomes. This is because a narrower scope lets you clarify the problem and study it at greater depth, whereas very broad research questions only allow a superficial treatment.

The research question can be formulated as one main question with (a few) more specific sub-questions or in the form of a hypothesis that will be tested.

Your research question will be your guide as your writing proceeds. If you are working independently, you are also free to modify it as you go along.

How do you know that you have drafted a research question? Most importantly, a research question is something that can be answered. If not, you have probably come up with a theme or field, not a question.

The most important research limitations in your work should be explained and why they are needed. This could for example relate to the fact that your work was focused on a certain target group, a certain architecture, a certain application. Normally, all research limitations must be valid assumptions and also motivated in the text.

due to lack of time: Most common used programming language that universities use in their courses are Java, the main focus will be on using the programming language Java and frameworks that fit Java.

## **1.5 Motivation "Objective" "Målsättning"**

In the motivation section the problem that has been studied should be briefly outlined and put in a context which clearly states why it is interesting and important to study in detail. The purpose is to make the reader interested of the work and create an eagerness to continue to read.

## **1.6 Outline "Översikt"**

The outline gives an overview of the main points of your thesis. It clarifies the structure of your thesis and helps you find the correct focus for your work. The outline can also be used in supervision sessions, especially in the beginning. You might find that you need to restructure your thesis. Working on your outline can then be a good way of making sense of the necessary changes. A good outline shows how the different parts relate to each other, and is a useful guide for the reader.

It often makes sense to put the outline at the end of the introduction, but this rule is not set in stone. Use discretion: What is most helpful for the reader? The information should come at the right point – not too early and not too late.





## 2.1 Introduction

Encyclopædia Britannica (EB) describes the general term *Artificial intelligence* (AI) as "*the ability of a digital computer or computer-controlled robot to perform tasks commonly associated with intelligent beings.*"[1]. The general broad concept of AI is to big and time consuming so a taxonomy of AI system must be understood to researcher on the correct parts. "the five tribes of machine learning" [5] is a taxonomy based on the type of problems they focus on.

1. Symbolists: whith a sufficient amount training sets and the power of logic and mathematical induction apply inverse deduction to solve the problems.
2. Connectionists: connected nodes or a neural network (NN) where each path from one neural to next is filled with a amount of tar sand. each time the neuron travels the wrong path that path is filled with more sand . Eventually it will be weary hard for the neurons to travel the wrong path. In programming terms a backpropagation algorithm is used to solve problems which involves matrices and weighted graphs.

3. evolutionaries: multilayer perceptrons that is NN model that maps sets of input data onto a set of appropriate outputs. continuously taking random choice and merging different nodes or reproducing/adapting and kill of the nodes resulting in unwanted outcome to fit the environment i inhabit.

4. Bayesians:

$$P(A|B) = \frac{P(A) \cdot P(B|A)}{n}$$

. Calculate probability of an events P(A) will occur based on prior knowledge of conditions that might be related that the event P(B)[6].

5. analogizers: kernel algorithms for pattern detection, matching pattern of one set of inputs and comparing it to the pattern of a known output. structure mapping or K-Nearest Neighbor (KNN) algorithms are fitting.

Before defining types algorithms to focus on, the data and problem must be understood. Experts will help to form the basis for defining how to solve the task of classifying the input data. before making assumptions and defining what parts of the five tribe taxonomy to implement the available data must be analyzed. Simple webscraping application was produces to download lates abilible warning leter and titel 21 CFR part 11 from <https://www.fda.gov/>

The chosen software class is dependent on analysis on the final product impact regarding patients health and safety versus drug benefits. Every part of the production must have a risk analysis of patients health and safety in case of digital signature errors, security breach, general errors, etc..

any new procedures for regulation of clinical software systems as medical devices requires detailed prior analysis of regulatory relevance to, or impact on, clinical software vendors, health care providers, and patients.

to be collected need to be analyzed.

Each classification panel in the CFR begins with a list of devices classified in that panel. Each classified device has a 7-digit number associated with it, e.g., 21 CFR 880.2920 - Clinical Mercury Thermometer. Once you find your device in the panel's beginning list, go to the section indicated: in this example, 21 CFR 880.2920 . It describes the device and says it is Class II. Similarly, in the Classification Database under "thermometer", you'll see several entries for various types of thermometers. The three letter product code, FLK in the database for Clinical

Mercury Thermometer, is also the classification number which is used on the Medical Device Listing form.

### **2.1.1 Introduction**



## METHOD, DESIGN AND IMPLEMENTATION

### **3.1 Introduction**

### **3.2 Prestudy**

### **3.3 Implementation**

### **3.4 Evaluation**

### **3.5 Conclusions**



CHAPTER



**RESULTS**

**4.1 Introduction**

**4.2 Conclusions**





## DISCUSSION

**5.1 Results****5.2 Method****5.3 AI in the future, moral,ethical,societal and economic view**

do not know what to call this section? In the thesis there should be a paragraph including a discussion about ethical and societal aspects related to the work. It is important to elevate the work to a professional level and show that the goals of your education programme and main subject area are met. If the work for some reason lacks any of these aspects it has to be explicitly mentioned in the Limitations section in the Introduction chapter.



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APPENDIX



APPENDIX A

**B**egins an appendix

