Autonomic Computing in Total Achievement of Quality

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Autonomic Computing Systemization of Knowledge

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Overview

This literature review style paper, considering the development of Autonomic Computing (AC) and the benefits for the domain of Quality Good "anything" Practice (GxP) manufacturing environments.

- Understanding the AC paradigm objectives and applications.
- The aim of Total Quality Achievement (TQA), the frameworks and standards supporting Quality practices in GxP environments.
- How computing systems support quality processes.
- Highlight applications of AC to computing, manufacturing and quality problems.
- Discuss future state, trust and ethics.

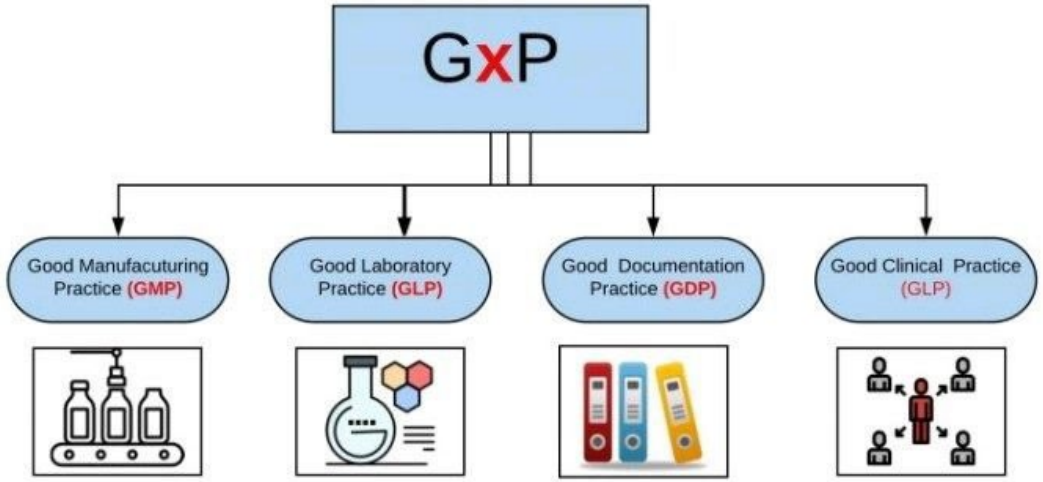

Fig. 1 GxP

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Autonomic Computing

• IBM envisioned the growth of computerised systems of systems, from the smallest edge to the largest datacentres and massively interconnected, as analogous to the human bodies smallest molecular machines with their signalling equipment and requiring the same capability to effortlessly integrate and self-manage.[1]

Fig. 2 System complexity

[1] A. G. Ganek and T. A. Corbi, "The dawning of the autonomic computing era", in IBM Systems Journal, vol. 42, no. 1, pp. 5-18, 2003, doi: 10.1147/sj.421.0005.
IBM, "An architectural blueprint for autonomic computing." IBM White Paper, 2006.

Autonomic Computing

- IBM outlined the problems that AC was seeking to address, the necessity for it and how it might be achieved. [2]
- They presented a case, that human progress has always depended upon technology and automation, freeing up human resources, to enable achieving bigger things.
- Computers and the IT industry have supported business and innovation to a certain point, but the rising complexity of these systems eventually presents a risk of even reversing these benefits.
- The human effort required to support these very same IT systems as they expand, rises exponentially and begins to reverse the human effort benefits. [3]
- The case is compelling and presents proposals for the capabilities an autonomic system should have, including Self-CHOP and MAPE-K framework.

Fig. 3 Autonomic Computing Self-CHOP

[2] P. Horn, “Autonomic Computing: IBM's Perspective on the State of Information Technology”, IBM Presentation, 2001.
[3] A. G. Ganek and T. A. Corbi, "The dawning of the autonomic computing era", in IBM Systems Journal, vol. 42, no. 1, pp. 5-18, 2003, doi: 10.1147/sj.421.0005.
IBM, "An architectural blueprint for autonomic computing." IBM White Paper, 2006.

Autonomic Computing

- Autonomic Managers (AM) interact with the individual managed elements of the system, achieved through the implementation of a "control loop", a framework for which was proposed in MAPE-K [3]
- **Monitor – "Sensors" inputs**
- **Analyse – evaluate input against existing values and optimise**
- **Plan – formulate policies**
- **Execute – output resultant policies through "Effectors"**
- **Knowledge - update**

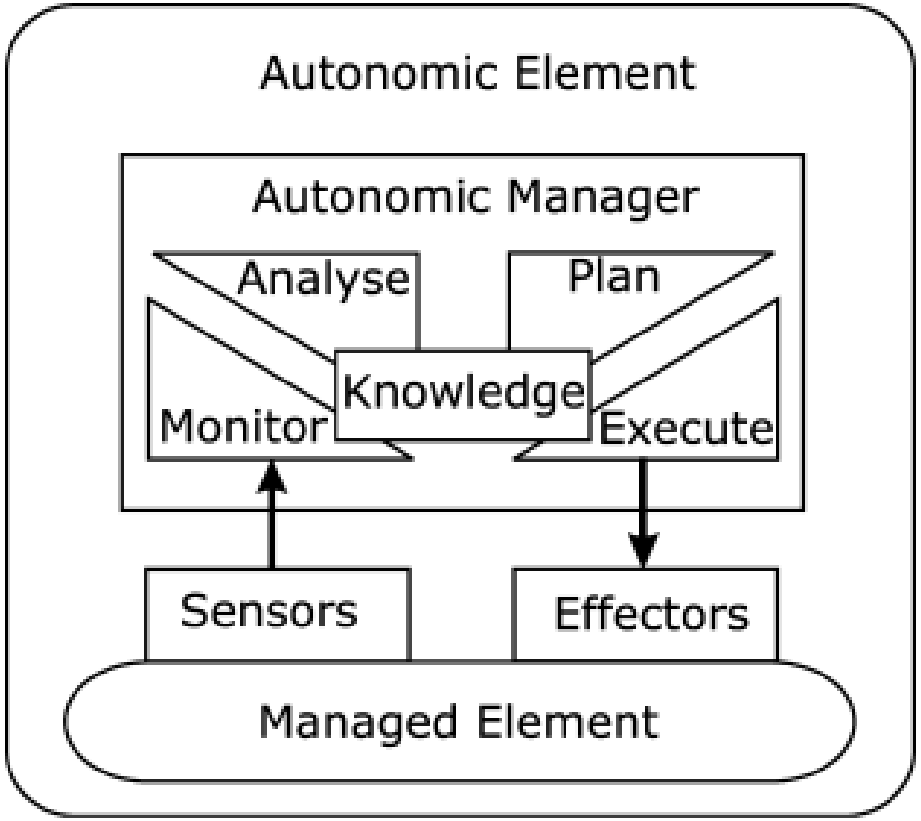


Fig. 4 MAPE-K intelligent control loop [5]

[4] IBM, "An architectural blueprint for autonomic computing." IBM White Paper, 2006.

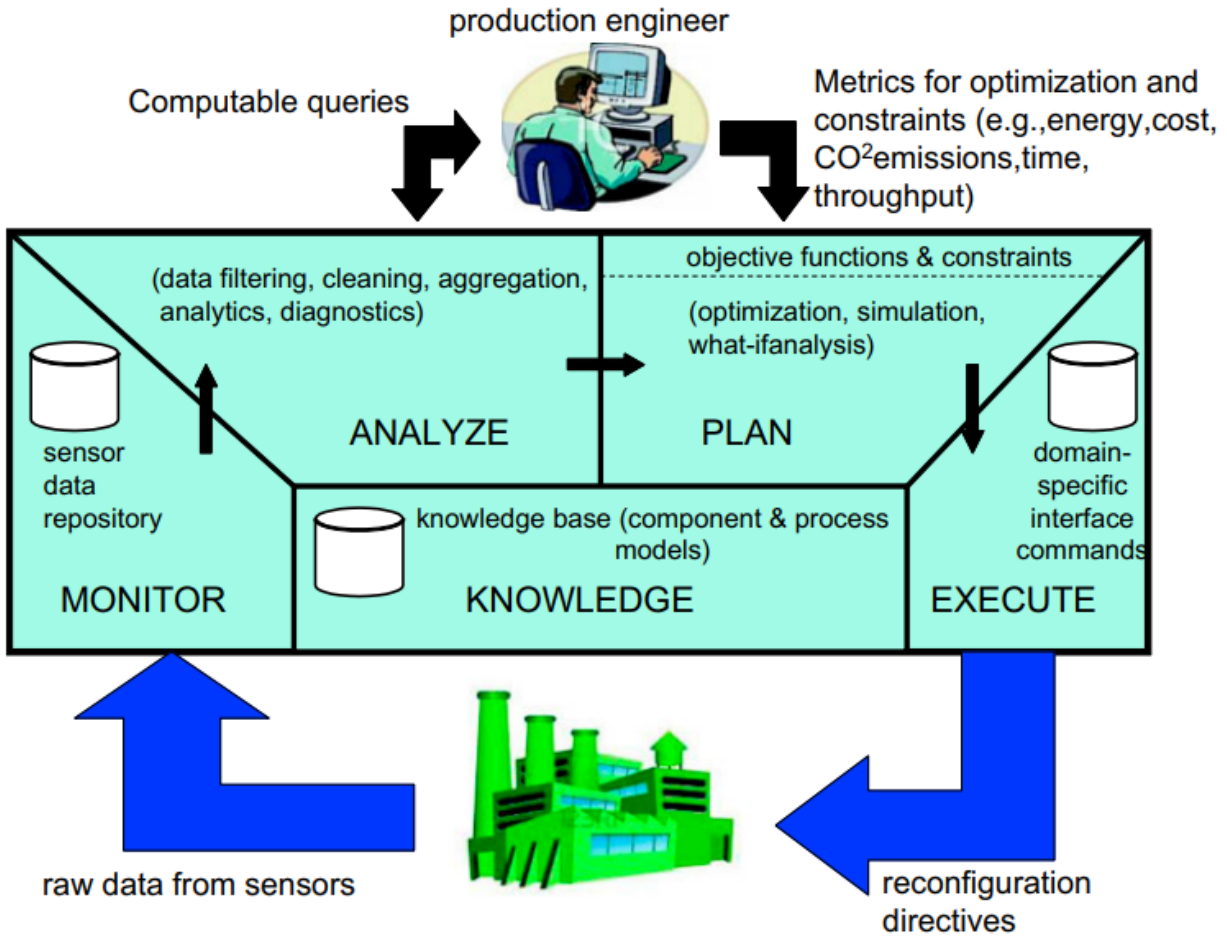
[5] M. C. Huebscher, and J. McCann, “A survey of autonomic computing—degrees, models, and applications”, ACM Comput. Surv., 40, 3, August 2008, DOI:10.1145/1380584.1380585.

Quality Systems - Manufacturing and Automation

- Manufacturing relies upon scheduling and execution, or a Manufacturing Execution System (MES).
- Typically, an MES system will provide some kind of feedback from manufacturing activities and outputs, together with a level of control to Management, e.g. if rejection limits are exceeded, they will be reported to the appropriate receiver [6].
- Computerised automation has greatly enhanced the ability of manufacturers to scale production and improve product quality. This results in increased system complexity.
- Tasks such as transfer of raw materials whether obtained, retained or disposed, must go through and from approved suppliers. In GxP compliant organisations, customers, manufacturers and suppliers must audit one another to ensure the validity of the supply chain end-to-end.
- Product manufacture may, for the most part, be described as automated, but is still heavily supported at almost every level by human activity and decision making.
- Every record pertaining to the manufacturing process, including, but not limited to documentation of batch records and product release must be retained and retrievable. This falls under Data Integrity (DI) standards to be discussed later.
- In MES and automation, we can see some parallel, with the problems IBM drew attention to in its early autonomic works on computing. AC integrated solutions have been proposed.

[6] D. A. Menascé, M. Krishnamoorthy, and A. Brodsky, “Autonomic smart manufacturing”, Journal of Decision Systems, 24:2, 206-224, 2015, DOI:10.1080/12460125.2015.1046714

Autonomic Smart Manufacturing



1. Fig. MAPE-K applied to smart manufacturing [7]

[7] D. A. Menascé, M. Krishnamoorthy, and A. Brodsky, "Autonomic smart manufacturing", Journal of Decision Systems, 24:2, 206-224, 2015, DOI:10.1080/12460125.2015.1046714

GxP Quality Systems - Product Testing

Product testing is not unique to GxP, but the burden of regulatory concerns is in many ways higher and must meet the requirements of internationally recognised standard QMS such as ISO9001. Product testing supports the development of production policies, as well as forming part of the batch release. Feedback to quality management results in a Continuos Improvement (CI) process.

Consider features in a typical laboratory setting,

- Product samples are taken from a batch, whether production, or a development cycle. The laboratory comprises a number of systems and instruments forming a testing suite.
- Instruments utilised must comply with national standards for regular calibration.
- Failed samples are reported against a batch, so that a determination can be made by quality assurance
- Analysis determines whether the sample test failure affects the whole batch, root cause and mitigations are fed back.
- The results of testing must be retained along with the records of any investigations.

Laboratory Information Management Systems (LIMS) support clerical activity around recording test results [8].

[8] J. E. H. Stafford, "LIMS: an automating or informating technology?", Laboratory Automation & Information Management,Volume 33, Issue 3, 1998, pp 163-168, doi:10.1016/S1381-141X(98)80002-6.

Quality Systems - Product Testing

Laboratory instrument machinery is largely automated once configured and validated, but experiments are selected manually, including the passing of results and aforementioned calibration. There are some existing autonomic-in-principal elements safe-guarding laboratory results and the instrumentation .

Examples

- Many instruments do not allow operation outside the pre-defined calibration windows.
- Internal sensors and diagnostics prevent operation if a fault is encountered, or if a part has passed its expiration date.
- Instrument are often modular to facilitate different kinds of experiments. If not needed, the module may be bypassed by the system.

We propose potential future states and roles for AC in this respect.

Quality Systems - Validation

The purpose of validation is per Good Automated Manufacturing Practice (GAMP) to provide documentary evidence and support a high level of confidence that all parts of a system will work correctly when used composed of various levels of qualification, which describe and contain activities to a system performs as specified. Qualifications include:

- Design Qualification (DQ) – documenting that all quality aspects of the system have been considered during the design of system
- Install Qualification (IQ) – ensures that a system has been installed per its specifications
- Operational Qualification (OQ) – the system functions operates as expected according to the tasks which have been identified
- Performance Qualification (PQ) – evidence that the system works on an ongoing basis in its final setting.

Security is also an important area of system validation, including that logins work correctly, since it has a direct bearing on the accuracy of records and traceability as per FDA Title 21 CFR Part 11. Data entry validation is also an important aspect, ensuring that data is formatted and saved appropriately, as well as being retrievable. Evidence for the tests having been carried out may also be required where this is part of the specification.

[9] D. Friedli, W. Kappeier, and S. Zimmermann, "Validation of computer systems: Practical testing of a standard LIMS", Pharmaceutica Acta Helvetiae, Volume 72, Issue 6, 1998, pp 343-348, DOI:10.1016/S0031-6865(97)00032-0.

Quality Systems - Validation

Summary

- Creation of design and test validation documents, collection of evidence and need for reviewers and approvers can be a lengthy and time-consuming process.
- Automation of systems has increased rather than decreased the level of effort required during validation, due to remaining distrust of automated systems, even when automated software testing is considered.
- Concerns about transparency arise, particularly when automation relies upon black box solutions where the underlying reasoning behind an activity cannot be directly observed.
- Improved automated testing and modelling can go some way toward allaying fears, such as injecting deliberate faults to see how the system handles different scenarios [10]
- Automated software testing is sometimes employed in validation, but automation can only get us so far.

We propose, it is nevertheless conceivable, that systems could become self-validating.

[10] C. Ebert, and M. Weyrich, “Validation of Autonomous Systems”, InfoQ, 2021, Available: https://www.infoq.com/articles/validation-autonomous-systems/, [Accessed 02.2024].

Quality Systems - Data Integrity

Integral to modern quality systems is Data Integrity (DI), that is data which meets standards of completeness, accuracy and consistency, i.e., the data must be ALCOA, i.e. attributable to a person or persons, legible, contemporaneous to what is being recorded, the original record and accurately recorded [11]. DI also requires consideration for how long records should be retained. On a computer, data can be in raw form, or processed form, yet even in the current state of a heavily computerised environment with relatively high levels of automation, original primary data records are often paper-based. As automation moves towards industry 4.0 smart manufacturing, much of the discussion inevitably turns to digitised data and data security.

A large concern in DI, is not just the maintenance of the original record, but the assurance of a validated backup and restore functionality, along with the data retention [12]

Another key component of quality systems data integrity since the late 90's is the Audit Trail. An audit trail provides evidence of actions performed by the system, or in the system. A weakness of the current audit trail implementations, is that they don't actually influence outcomes, but merely record activities. A security audit trail records that a user/system login took place, or that a particular record was saved by a given logged in user at a given time, but it is often a flat text log file, which doesn't have any actual connection to the potentially affected data records.

[11] H. Alosert, et. al., "Data integrity within the biopharmaceutical sector in the era of Industry 4.0", Biotechnology Journal, 17, 2022, DOI:10.1002/biot.202100609.
[12] Ronolo, S.C., "Assuring Data Integrity towards Regulatory Compliance: A Study on Process Improvement in Data Integrity Compliance of Computerized Systems.", May 2023

Quality Systems - Data Integrity (Blockchain)

A type of database paradigm which seems set to address the limitations of traditional database and logging systems in this respect is blockchain technology. The underlying principles of a blockchain are essentially autonomic.

- **A blockchain database consists of a series of blocks, to which any kind of data can be written, encrypted by a hash. Every subsequent entry relies on the hash of the previous block to decrypt, forming an effectively immutable chain. It is impossible to update the historical blocks without possessing every single cryptographic hash key, so it is self-protecting and trustworthy. With respect to data blockchains require no human maintenance once started.**
- **Entries are time-stamped and signed by a unique identifier which indicates ownership of the record.**
- **Sophisticated blockchains integrate so-called smart contracts which are automatically executed on-chain once agreed between parties.**
- **Nodes host identical copies of the chain and increase the reliability of the network and bandwidth, whilst providing internal consensus that block transactions committed to the database are valid. Self-healing - any potential corruption, or invalid blocks are eliminated by comparison with other nodes.**
- **Blockchains are largely self-configuring, automatically integrating new nodes.**
- **Blockchains can include apoptotic self-destruction of transactions once these have expired, which automatically releases the storage utilised by the transaction block.**

Given these properties, it isn't surprising a framework for utilising blockchain in an ISO compliant QMS to achieve Total Quality Management (TQM) has already been suggested [13], but we propose it would seem particularly suitable for ensuring contemporaneous association of data records with a digital identification, as per the requirements of DI, without the need for a separate audit trail.

[13] R. Muruganandham, K. Venkatesh, S. R. Devadasan, and V. Harish "TQM through the integration of blockchain with ISO 9001:2015 standard based quality management system", Total Quality Management & Business Excellence, 34:3-4, pp 291-311, 2023, doi: 10.1080/14783363.2022.2054318

Quality Systems - Supporting IT Infrastructure

Finally, although some of the areas above have touched upon the associated IT technologies which support the various quality processes, a brief consideration of how IT infrastructure as a whole supports these systems and how IT has benefited and may yet benefit from autonomicity to support quality seems appropriate.

IT Infrastructure refers to all of the components necessary to deliver IT services within an organisation, e.g. equipment, network, software and services, including Internet based services and datacenters [14].

A subset of IT Infrastructure examples are briefly considered in the paper, which have been selected due to suitable existing and potential AC properties

- Storage
- Network
- Servers
- Data Centres/Cloud

[14] Laan, Sjaak. “IT infrastructure architecture-infrastructure building blocks and concepts second edition”. Sjaak Laan, 2012.

Conclusion

- In reviewing the state of Quality systems and AC, there seemed to be remarkable parallels between the steps and goals used in TQM and the descriptions of AC processes, such that AC can be envisioned in the various frameworks performing the same functions which are currently requiring a high level of human input.

- The need for more autonomicity in the various components of the quality system is apparent, but so is the difficulty of overcoming concerns around trust and accountability.

- There are some ethical concerns around impacts upon job satisfaction, when autonomous systems add autonomic, as it has been noted that the introduction of LIMS "led to an explosion of paperwork" and that automation "usurped" any control/autonomy a worker had and handed it directly to management [8].

- It was noteworthy, that a lot of literature tends to focus upon the potential for autonomous aspects of systems, perhaps enabled by machine learning and not necessarily the autonomicity of the systems which will allow them to function independently in a trusted way.

- Among emerging technologies, Blockchain is an exciting autonomic development which may gain traction in quality environments future state, where ultimate performance is not the highest concern.

- Open autonomic standards [1] will continue to be a way forward and crucial to allowing Quality environments to trust and utilise AC. In the authors' view, the achievement of AC and TQA will mature together.

[8] J. E. H. Stafford, "LIMS: an automating or informating technology?", Laboratory Automation & Information Management, Volume 33, Issue 3, 1998, pp 163-168, doi:10.1016/S1381-141X(98)80002-6.
[1] A. G. Ganek and T. A. Corbi, "The dawning of the autonomic computing era", in IBM Systems Journal, vol. 42, no. 1, pp. 5-18, 2003, doi: 10.1147/sj.421.0005.

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Joel is continuing this research by undertaking a MSc Dissertation on "Supervision of Quality Environments with an Autonomic Ledger".

Thank You

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